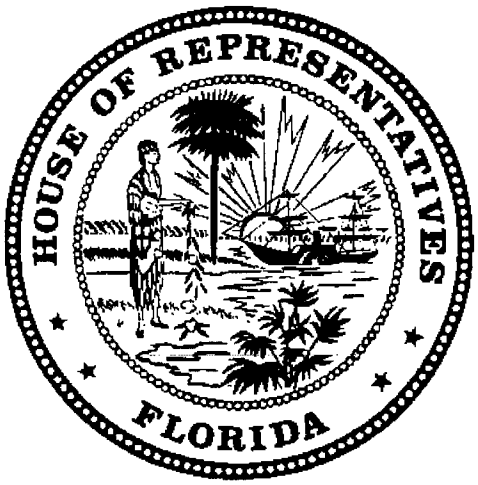

Health Care Regulation Committee

Wednesday, March 15, 2006
8:45 AM - 11:00 AM
212 Knott Building

Allan G. Bense
Speaker

Rene Garcia
Chair

House of Representatives

Committee on Health Care Regulation

AGENDA

March 15, 2006
8:45 AM - 11:00 AM
212 Knott Building

I. Opening Remarks by Chair Garcia

II. Consideration of the following bills:

HB 181 – Administration of Medication by Rep. Hays

HB 715 – Trauma Services by Rep. Grimsley

HB 859 – Physician Assistants by Rep. Baxley

HB 881 – Physician Licensure Requirements by Rep. Flores

HB 7045 – Review under the Open Government Sunset Review Act regarding Supplemental Rebate Agreements by Governmental Operations Committee

III. Consideration of the following Proposed Committee bills:

PCB HCR 06-02 – Licensure of Health Care Providers

PCB HCR 06-04 – Electronic Prescribing

IV. Closing Remarks

V. Adjournment

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 181 Administration of Medication
SPONSOR(S): Hays
TIED BILLS: **IDEN./SIM. BILLS:** SB 170

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Elder & Long-Term Care Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 181 allows unlicensed direct care services staff to administer prescription medications to persons with developmental disabilities who reside in a comprehensive transitional education program, under the general supervision of a registered nurse.

The bill allows such programs to train unlicensed direct care staff to administer or assist in administering oral, otic, transdermal, ophthalmic, inhaled, rectal or topical prescription medications.

The bill provides an exemption to the Nurse Practice Act, which allows unlicensed direct care providers to administer medication without fear of prosecution for practicing nursing without a license. The nursing practice act does not prohibit a registered nurse or licensed practical nurse from delegating the administration of medication, but does require the nurse to determine the competency of the unlicensed person.

The bill expands the existing provision (s. 393.506, F.S.) for unlicensed direct care staff to include the administration of otic, ophthalmic and rectal prescription medications.

Current statute, (ss. 400.488, 400.4256, 400.9685, and 1006.062, F.S.) provides statutory authority with specific guidelines for unlicensed individuals to administer medication. Sections 400.488 and 400.4256, F.S., specifically state that assistance with self-administration does not include administration of rectal medications. These sections also limit the administration of medications by unlicensed care providers, and prohibit the administration of medications where judgment or discretion is needed to determine the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration. The bill does not include any specific guidelines or limitations that are provided in statute for other entities.

The bill also changes "day programs" to "day habilitation services" to reference existing definitions within ch. 393, F.S, and provides the Agency for Persons with Disabilities the authority to promulgate rules.

Fiscal Impact: This bill does not appear to have a fiscal impact on state or local governments.

This bill will take effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Safeguard individual liberty-Increases the options for a comprehensive transitional education program to provide care to their clients. This may adversely affect a client's safety if the unlicensed direct care staff is not sufficiently trained.

B. EFFECT OF PROPOSED CHANGES:

The bill allows comprehensive transitional education programs to train unlicensed direct care services staff to administer or assist in administering oral, otic, transdermal, ophthalmic, inhaled, rectal or topical prescription medications to persons with developmental disabilities, under the general supervision of a registered nurse.

The bill provides an exemption to the Nurse Practice Act, which allows the unlicensed direct care staff to administration medication without fear of prosecution for practicing nursing without a license.

The bill expands the existing provision (s. 393.506, F.S.) for unlicensed direct care staff to include the administration of otic, ophthalmic and rectal prescription medications.

Current statute, (ss. 400.488, 400.4256, 400.9685, and 1006.062, F.S.) provides statutory authority, with specific guidelines, for unlicensed individuals to administer medication. Sections 400.488 and 400.4256, F.S., specifically state that assistance with self-administration does not include administration of rectal medications. These sections also limit the administration of medications by unlicensed care providers and prohibit the administration of medications where judgment or discretion is needed to determine the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration. The bill does not include the specific guidelines or limitations that are provided in statute for other entities.

The bill changes "day programs" to "day habilitation services" to reference existing definitions within ch. 393, F.S, and provides the Agency for Persons with Disabilities with the authority to promulgate rules.

PRESENT SITUATION

Nurse Practice Act, Supervision and Delegation of Authority

The nursing practice act and rules do not expressly prohibit a registered nurse or licensed practical nurse from delegating the administration of medication but, in effect, requires the nurse to determine the competency of the unlicensed person who is delegated any nursing task or activity, to ensure that the person is competent and that the person's competency has been validated.

Chapter 464, Part I, F.S., provides for the regulation of nursing in Florida by the Board of Nursing in the Department of Health. The board has adopted administrative rules relating to the delegation of tasks to unlicensed assistive personnel.[1]

These rules provide that a registered nurse or licensed practical nurse must use nursing judgment in considering the task or activity to be delegated. The delegation process must include communication to the unlicensed assistive personnel to identify the task or activity, the expected or desired outcome, the limits of authority, the time frame for the delegation, the nature of the supervision required, verification that the delegate understands the assignment, verification of monitoring, and supervision.

[1] See Chapter 64B9-14, Florida Administrative Code.

A registered nurse or licensed practical nurse may *not* delegate activities that are not within the delegating or supervising nurse's scope of practice.

Nursing activities that require the special knowledge and use of nursing processes, judgment, or skills of a registered or practical nurse, may *not* be delegated to unlicensed assistive personnel.

Examples of such nursing activities that may *not* be delegated include:

- initial nursing assessment or any subsequent assessments;
- determination of the nursing diagnosis or interpretations of nursing assessments;
- establishment of nursing care goals and development of the plan of care; and
- evaluation of progress in relationship to the plan of care.

Comprehensive Transitional Education Program

Currently, there is one comprehensive transitional education program licensed in Florida.[2] The comprehensive transitional educational program is a large program that has the capacity to serve as many as 120 residents who reside in smaller residential units in three locations. According to the program, they currently provide services to 91 residents, of whom at least 97% take some type of medication. According to the website for the program, it treats clients who have been diagnosed with conditions such as autism, developmental disabilities, severe emotional disturbances, dual diagnoses, conduct disorders and other related diagnoses.[3]

The facility currently has (1) full-time registered nurse and (1) licensed practical nurse on staff. These individuals are available 24-hours a day. Over the weekends (2) Registered Nurses are on call. According to the facility, all unlicensed direct care staff are required to attend training on how to administer medications and identify adverse reactions. The training is administered locally and the participants receive a certificate of completion.

Chapter 393, F.S., defines "comprehensive transitional education program" to mean a group of jointly operating centers or units, the collective purpose of which is to provide a sequential series of educational care, training, treatment, habilitation, and rehabilitation services to persons who have developmental disabilities and who have severe or moderate maladaptive behaviors. The services that are provided by a comprehensive transitional education program must be temporary in nature and delivered in a structured residential setting with the primary goal of incorporating the normalization principle to establish permanent residence for persons with maladaptive behaviors in facilities not associated with the program.[4]

Section 393.063, F.S., defines "developmental disability" as a disorder or syndrome that is attributable to retardation, cerebral palsy, autism, spina bifida, or Prader-Willi syndrome and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.

The services provided by the comprehensive transitional education program are funded under a Medicaid program waiver.

Surrogate Family and Smaller Residential Settings

In smaller residential settings, properly trained persons or direct care staff may administer medications, as long as smaller residential settings function as a surrogate family. Under current statute incidental care may be provided to sick or non-institutionalized persons, as long as the care is performed by

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[2] Advoserv-Carlton Palms, *Our Florida Locations*, available at http://www.advoserv.com/florida.html (January 4, 2006).
[3] Ibid.
[4] See s. 393.062(7), F.S.

friends or members of the family, domestic servants, or a surrogate family.[5] This provision provides an exemption to the Nurse Practice Act, which allows unlicensed care to provide care to a surrogate family member without fear of prosecution for practicing nursing without a license.

In day programs, the director of a facility or program must designate in writing that an unlicensed direct care services staff is eligible to be trained in how to assist in the administration or is able to administer medication directly.[6]

In an intermediate care facility, the director of a facility or program for the developmentally disabled may designate unlicensed staff that may provide medication assistance under the general supervision of a Florida-licensed registered nurse.[7]

Types of Medications Administered to Persons with Developmental Disabilities

Currently, the administration of medication to persons with developmental disabilities in the comprehensive transitional educational program is performed by a nurse. The bill allows unlicensed direct care staff to administer medication under the general supervision of a registered nurse in such programs.

Currently, in day programs and intermediate care facilities, unlicensed direct care staff may administer oral, transdermal, inhaled or topical prescription medications to persons with developmental disabilities.[8] The bill expands this provision by allowing unlicensed direct care services to include the administration of otic, ophthalmic and rectal prescription medications.

Training Requirements of Unlicensed Direct Care Staff

Each facility, institution, or program under the purview of s. 393.506, F.S., must include in its policies and procedures a plan for training designated staff to ensure the safe handling, storage, and administration of prescription medication. These policies and procedures must be approved by the Agency for Persons with Disabilities before an unlicensed direct care staff assists with the administration of medication. The policies and procedures must include, at a minimum, the following provisions:

- An expressed and informed consent for each client;
- The director of the facility, program, or provider must maintain a copy of the written prescription, and that prescription must include the name of the medication, the dosage and administration schedule, the reason for the prescription, and the termination date; and
- Each prescribed medication must be kept in its original container and in a secure location.

The training required in s. 393.506, F.S., must be conducted by a registered nurse or a Florida-licensed medical physician or osteopathic physician.

Clarification of Terminology for Day Programs and Day Habilitation Facilities

Section 393.506, F.S., refers to "day programs" as defined in s. 393.063, F.S., but s. 393.063, F.S., does not define "day programs." Section 393.063(8), F.S., does define "day habilitation facility" and "day habilitation services." The bill corrects the inconsistency in terminology.

- A "day habilitation facility" is defined as any nonresidential facility which provides day habilitation services.

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[5] See s. 464.022(1), F.S.
[6] See s. 393.506, F.S.
[7] Ibid.
[8] See s. 393.506, F.S.

- A "day habilitation service" is defined as a service that provides assistance with the acquisition, retention, or improvement in self-help, socialization, and adaptive skills which takes place in a nonresidential setting, separate from the home or facility in which the individual resides. Day habilitation services shall focus on enabling the individual to attain or maintain his or her maximum functional level and shall be coordinated with any physical, occupational, or speech therapies listed in the plan of care.

C. SECTION DIRECTORY:

Section 1. Amends s. 393.506, F.S., relating to the administration of medication by unlicensed direct care staff in a comprehensive transitional education program, and grants rule making authority to the Agency for Persons with Disabilities.
Section 2. Provides the bill will take effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The Comprehensive Transitional Education Program (CTEP) may economically benefit from implementation of this bill. They would no longer be required to have medications administered by a nurse and may be able to decrease their nursing staff.

D. FISCAL COMMENTS:

There may be costs associated with rule promulgation by the Agency for Persons with Disabilities.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

This bill provides the Agency for Persons with Disabilities the authority to adopt rules to facilitate implementation.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, the Board of Nursing has client safety concerns regarding the administration of medications by unlicensed personnel and feels that any authority to do so should mimic the requirements for education/training and supervision by a registered nurse as provided in chapter 400, F.S.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to the administration of medication; amending s. 393.506, F.S.; authorizing certain staff members to administer prescription medications under the supervision of a registered nurse to persons with developmental disabilities at a comprehensive transitional education program; directing the Agency for Persons with Disabilities to adopt rules to implement s. 393.506, F.S.; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 393.506, Florida Statutes, is amended to read:

393.506 Administration of medication.--

(1) Notwithstanding the provisions of part I of chapter 464, the Nurse Practice Act, unlicensed direct care services staff providing services to persons with developmental disabilities may administer oral, transdermal, inhaled, or topical prescription medications as provided in this section.

(a) For day habitation services ~~programs~~, as defined in s. 393.063, the director of the facility or program shall designate in writing unlicensed direct care services staff who are eligible to be trained to assist in the administration of or to administer medication.

(b) For intermediate care facilities for the developmentally disabled licensed pursuant to part XI of chapter 400, unlicensed staff designated by the director may provide

medication assistance under the general supervision of a registered nurse licensed pursuant to chapter 464.

(2) Notwithstanding part I of chapter 464, the Nurse Practice Act, unlicensed direct care staff who provide services to persons with developmental disabilities in a comprehensive transitional education program licensed pursuant to s. 393.067 and who are designated by the director of such program may administer, or assist in the administration of, oral, otic, transdermal, ophthalmic, inhaled, rectal, or topical prescription medications under the general supervision of a registered nurse licensed pursuant to chapter 464 as provided in this section.

(3) ~~(2)~~ Each facility, institution, or program must include in its policies and procedures a plan for training designated staff to ensure the safe handling, storage, and administration of prescription medication. These policies and procedures must be approved by the agency before unlicensed direct care services staff assist with medication.

(4) ~~(3)~~ The policies and procedures must include, at a minimum, the following provisions:

(a) An expressed and informed consent for each client.

(b) The director of the facility, program, or provider must maintain a copy of the written prescription, and that prescription must include the name of the medication, the dosage and administration schedule, the reason for the prescription, and the termination date.

(c) Each prescribed medication shall be kept in its original container and in a secure location.

(5)~~(4)~~ The training required in this section shall be conducted by a registered nurse or a physician licensed pursuant to chapter 458 or chapter 459.

(6) The Agency for Persons with Disabilities shall adopt rules to implement this section.

Section 2. This act shall take effect upon becoming a law.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 181**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Hays offered the following:

Amendment (with directory and title amendments)

Remove everything after the enacting clause and insert:

Section 1. Section 393.506, Florida Statutes, is amended to read:

393.506 Administration of medication.--

(1) A ~~Notwithstanding the provisions of part I of chapter 464, the Nurse Practice Act, unlicensed~~ direct service provider who is not currently licensed to administer medication ~~care services staff providing services to persons with developmental disabilities~~ may supervise the self-administration of or may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, or topical prescription medications to a client as provided in this section.

(2) In order to supervise the self-administration of medication or to administer medications as provided in subsection (1), a direct service provider must satisfactorily complete a medication administration training course of not less

than 4 hours in medication administration and be found competent to supervise the self-administration of medication by a client or to administer medication to a client in a safe and sanitary manner. Competency must be assessed and validated at least annually in an onsite setting and must include personally observing that the direct service provider satisfactorily:

(a) Supervised the self-administration of medication by a client.

(b) Administered medication to a client.

(3) A direct service provider may supervise the self-administration of medication by a client or may administer medication to a client only if the client, or the client's guardian or legal representative, has given his or her informed consent to self-administering medication under the supervision of an unlicensed direct service provider or to receiving medication administered by an unlicensed direct service provider. Such informed consent must be based on a description of the medication routes and procedures that the direct service provider is authorized to supervise or administer. Only a direct service provider who has received appropriate training and has been validated as competent may supervise the self-administration of medication by a client or may administer medication to a client.

(4) The determination of competency and annual validation required under this section shall be conducted by a registered nurse licensed pursuant to chapter 464.

(5) The agency shall establish by rule standards and procedures that a direct service provider must follow when supervising the self-administration of medication by a client and when administering medication to a client. Such rules must,

at a minimum, address requirements for labeling medication, documentation and recordkeeping, the storage and disposal of medication, instructions concerning the safe administration of medication or supervision of self-administered medication, informed-consent requirements and records, and the training curriculum and validation procedures.

~~(a) For day programs, as defined in s. 393.063, the director of the facility or program shall designate in writing unlicensed direct care services staff who are eligible to be trained to assist in the administration of or to administer medication.~~

~~(b) For intermediate care facilities for the developmentally disabled licensed pursuant to part XI of chapter 400, unlicensed staff designated by the director may provide medication assistance under the general supervision of a registered nurse licensed pursuant to chapter 464.~~

~~(2) Each facility, institution, or program must include in its policies and procedures a plan for training designated staff to ensure the safe handling, storage, and administration of prescription medication. These policies and procedures must be approved by the agency before unlicensed direct care services staff assist with medication.~~

~~(3) The policies and procedures must include, at a minimum, the following provisions:~~

~~(a) An expressed and informed consent for each client.~~

~~(b) The director of the facility, program, or provider must maintain a copy of the written prescription, and that prescription must include the name of the medication, the dosage and administration schedule, the reason for the prescription, and the termination date.~~

~~(c) Each prescribed medication shall be kept in its original container and in a secure location.~~

~~(4) The training required in this section shall be conducted by a registered nurse or a physician licensed pursuant to chapter 458 or chapter 459.~~

Section 2. This act shall take effect upon becoming a law.

========== T I T L E A M E N D M E N T ==========

Remove the entire title and insert:

A bill to be entitled

An act relating to administration of medication; amending s. 393.506, F.S.; deleting requirements for unlicensed staff members of direct care service facilities to administer prescribed medications to persons with developmental disabilities; authorizing direct service providers to administer medication to clients or to supervise the self-administration of medication by clients; providing requirements for direct service providers to demonstrate competency regarding supervising the self-administration of medication by clients or administering medication to clients; requiring the Agency for Persons with Disabilities to adopt rules to establish standards and procedures governing the supervision of self-administered medications and the administration of medications by direct service providers; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 715 Trauma Services
SPONSOR(S): Grimsley
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

In the 2005 session the Legislature passed HB 715 and HB 1697, which provided additional funding to trauma centers through traffic infraction fines and court assessments. Revenues generated through these additional funds are appropriated into the Department of Health Administrative (DOH) Trust Fund, from which up to $7.5 million is earmarked to provide funding for trauma centers on the basis of caseload and the severity of trauma patients. Currently, $1 million dollars has been raised by the increased fee.

HB 715 addresses the allocation and distribution of trauma center funds. The bill changes a number of provisions related to the distribution and determination of trauma payments to current verified trauma centers. The changes include:

- Requires an annual audit of trauma registry data;
- Changes the way trauma centers determine the severity of patients (by requiring trauma centers to evaluate patients with the International Classification Injury Severity Score (ICISS) instead of the Injury Severity Score (ISS); and
- Provides definitions for ICISS, trauma caseload volume, and trauma patient.

The Department of Health (DOH) estimates that the fiscal impact of the oversight provisions of the bill is $844,327 in the first year and $877,361 in the second year.

The effective date of the bill is July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote Limited Government – The bill provides new definitions, changes the way verified trauma centers determine the severity of trauma patients that may alter the distribution of trauma center funds, and requires a yearly independent audit of the trauma registry data. The Department of Health estimates that the fiscal impact of the bill auditing requirements is $844,327 in the first year and $877,361 in the second year.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

In the 2005 session the Legislature passed HB 715 and HB 1697, both of which provide additional funding to trauma centers through traffic infraction fines and court assessments. HB 715 increased the civil penalties for drivers who failed to obey red traffic signals from $60 to $125. HB 1697 allocated funds from mandatory civil penalties to this same DOH Administrative Trust Fund, to provide financial support to trauma centers throughout the state.

Revenues generated through these additional funds are appropriated into the Department of Health Administrative (DOH) Trust Fund, from which up to $7.5 million is earmarked to provide funding for trauma centers on the basis of caseload and the severity of trauma patients. Currently, $1 million dollars has been raised by the increased fee.

Trauma center funding is weighted based on the severity of trauma patients (40%), the trauma caseload volume (40%), and availability of local funding contributions (20%). The severity of trauma patients is determined by the ISS score and the caseload volume is determined by DOH's Trauma Registry Data.

The severity of trauma patients and caseload volume is collected and entered into the Department of Health Trauma Registry. The classification currently used to rate severity of trauma is the Injury Severity Score (ISS).

Trauma Registry data is currently verified by DOH staff during the yearly trauma center site survey. The DOH survey takes a very small sample of Trauma Registry records to evaluate trauma staffing and procedures. This survey does not focus on the validity of the Trauma Registry ISS.

Currently, funds collected for distribution to trauma centers are based on the calendar year and not the state fiscal year.

Effects of the Bill

HB 715 amends ss. 395.404 & 395.4035, F.S., to address the allocation of trauma center funds. It changes a number of provisions related to the determination and distribution of trauma payments to current verified trauma centers.

The bill requires an independent entity to annually audit the Trauma Registry data and to submit the audit report to the Department of Health (DOH).

The bill changes the standard by which trauma centers report injuries to DOH. Currently the severity of trauma patients is determined and coded with Injury Severity Scores (ISS), which only considers a maximum of three patient injuries. The bill requires trauma severity to be determined by the International Classification Injury Severity Scores (ICISS), the current standard, and other statistically

valid and scientifically accepted methods of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by DOH by rule. The impact of the change in injury determination methodology may change payment calculations for determining the amount of funding allotted to each trauma center.

The bill provides that DOH's Administrative Trust Fund may be used to maximize federal funds available to trauma centers. The total funds distributed to trauma centers may include revenue from DOH's Administrative Trust Fund and federal funds for which revenue from DOH's Administrative Trust Fund is used to meet state or local matching requirements, including Medicaid.

The bill changes the period for distribution of funds from calendar year to state fiscal year.

The bill repeals s. 395.4035, F.S., the Trauma Trust Fund. This has no impact on trauma centers because the Trauma Trust Fund has never been used by DOH. Funds collected for distribution to trauma centers have been deposited into either the Emergency Medical Services Trust Fund or the DOH Administrative Trust Fund.

The bill amends s. 395.4001, F.S., to provide definitions for the International Classification Injury Severity Score (ICISS), trauma caseload volume, and trauma patient. These are new statutory definitions.

The effective date of the bill is July 1, 2006.

BACKGROUND

Chapter 395, F.S., defines a trauma center as a facility within a general medical hospital determined by the Department of Health to be in compliance with trauma center verification standards. These centers treat individuals who have incurred blunt or penetrating injuries or burns, and who require immediate medical intervention and treatment. Trauma center patients require urgent, lifesaving care. Trauma centers must be ready at all times and have designated suites reserved to treat patients at all times. Emergency rooms are not trauma centers. A trauma center has dozens of specialists, many of whom are available 24-hours-a-day, seven days a week. Trauma centers have access to air emergency whose job is to be available for the moment a serious accident occurs.

The effectiveness of a trauma center lies in the speed and quality of treatment. Getting a patient definitive care within the first hour, or golden hour, of injury drastically increases their chances of survival. Trauma mortality is reduced by 15-20% when a very seriously injured patient is treated at a trauma center versus a non-trauma center.

Florida's trauma system has been under development since the passage of landmark trauma legislation in the late 1980's. Key components of this system include trauma centers, trauma agencies, trauma service areas, and trauma regions, as well as trauma transport protocols and trauma triage criteria for emergency medical service providers.

Florida Trauma Registry

The Florida Trauma Registry (FTR) collects patient-level data from the state's twenty-one trauma centers. As a state designated facility, a trauma center must maintain a comprehensive database of those injured patients treated within the hospital. The trauma registry supports the trauma centers required activities, including performance improvement, outcomes research, and resource utilization as well as providing the state public health system with the necessary data for state-wide planning and injury prevention initiatives.

Comparing the ISS and the ICISS

Characterization of injury severity is crucial to the study and treatment of trauma. The measurement of injury severity began just over 50 years ago with the Abbreviated Injury Scale (AIS), a method developed to grade the severity of individual injuries. The AIS has been modified many times, most recently in 1990, and is the basis for the Injury Severity Score (ISS). The Injury Severity Score (ISS) was for many decades the standard summary measure of human trauma. However, it has two weaknesses. First, the ISS considers a maximum of only three of an individual patient's injuries which may not even be the patient's most severe injuries. Second, the ISS requires that all patients have their injuries described using an expensive assessment method unavailable at most hospitals, especially those that do not specialize in trauma.[1]

A more recent approach to injury scoring is based on the *International Classification of Disease, Ninth Edition* (*ICD-9*) codes and is referred to as the *ICD-9* Injury Severity Score (ICISS). The ICISS is a data-driven alternative to ISS that uses empirically-derived injury severity measures, and considers all of an individual patient's injuries rather than just a few. The use of the standard ICD-9 classification scheme adds to the statistical appeal of the ICISS and avoids the need for costly AIS coding.[2]

In terms of methodology, the ICISS uses survival risk ratios (SRRs) calculated for each *ICD-9* discharge diagnosis. SRRs are derived by dividing the number of survivors in each *ICD-9* code by the total number of patients with the same *ICD-9* code. ICISS is calculated as the simple product of the SRRs for each of the patient's injuries.[3] For example, if a population of 1,000 patients with femoral fractures included 100 patients who died, then the single SRR for that particular diagnoses would be .9 or [1-(100/1000)]. A patient with two injuries, one having a SRR of .9 and the other having a SRR of .5, would have a total probability of survival of .9 multiplied by .5, yielding an overall probability of survival of .45.[4]

ICISS has demonstrated a greater reliability than ISS, and offers many advantages for predicting the severity of an illness and injury. The ICISS values may also be used as predictors of resource utilization, and may be used as an assessment tool in quality improvement efforts. Research has shown benefits of the ICISS over other scoring systems include:[5]

1. It represents a true continuous variable that takes on values between 0 and 1.
2. It includes all injuries.
3. *ICD-9* codes are readily available and do not require special training or expertise to determine.
4. *ICD-9* has better predictive power when compared to the ISS.
5. ICISS has the potential to better account for the effects of comorbidity on outcome by including the SRR for each comorbidity present.
6. The ICISS outperforms the ISS in predicting other outcomes of interest (e.g., hospital length of stay, hospital charges).
7. Compared to all over available severity adjustment systems, ICISS was most accurate.
8. ICISS can be more precisely population-based.
9. ICISS requires no additional software manipulation of data. ICDMAP-90 software for risk stratification converts International Classification of Disease (ICD) discharge diagnoses to injury severity scores to allow standardized outcome comparison.

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[1] Osler, T., Rutledge, R., et al. ***ICISS*: An International Classification of Disease-9 Based Injury Severity Score.** *Journal of Trauma-Injury Infection & Critical Care.* 41(3):380-388, September 1996. Available online at http://www.jtrauma.com/.

[2] Sposato, E.M. "The End of the Injury Severity Score (ISS) and the Trauma and Injury Severity Score (TRISS): ICISS, an International Classification of Diseases, Ninth Revision-Based Prediction Tool, Outperforms Both ISS and TRISS as Predictors of Trauma Patient Survival, Hospital Charges, and Hospital Length of Stay. *Journal of Trauma Nursing.* Jan-March, 1999. Available online at http://www.allbusiness.com/periodicals/article/350114-1.html

[3] Offner, P. Trauma Scoring Systems. *EMedicine.* 4/25/02. http://www.emedicine.com/med/topic3214.htm

[4] https://jobs.orhs.org/trauma/report-feb-05.pdf

[5] http://www.emedicine.com/med/topic3214.htm and https://jobs.orhs.org/trauma/report-feb-05.pdf

C. SECTION DIRECTORY:

Section 1. – Amends s. 395.4001, F.S., to provide definitions.

Section 2. – Repeals s. 395.4035, F.S.

Section 3. – Amends s. 395.4036, F.S., to require that funds distributed to trauma centers be based on audited Trauma Registry caseload volume for the previous calendar year.

Section 4. – Amends s. 395.404, F.S., to require an independent entity to audit the Trauma Registry data.

Section 5. – Provides the bill will take effect July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

Department of Health Estimated Expenditures		(Annualized/Recurr.)
Salaries		
1 Operations & Management Consultant II @ $35,668	$34,241	$45,655
1 Computer System Analyst @ $30,021 (FTE computed w/28% fringe and 25% lapse)	$28,820	$38,426
Expense		
2 FTE @ std DOH professional Pkg. w/limited travel @ $13,733	$27,466	$20,780
Independent Entity Contract for Audit of Trauma Registry Data	$750,000 (estimated)	$772,500 (5% estimated inflation)
Operating Capital Outlay		
2 FTE @ Std DOH professional pkg.	$3,800	$
Total Estimated Expenditures	**$844,327**	**$877,361**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill alters the way trauma centers determine the severity of trauma patients. Forty percent of trauma center funding is distributed by the ISS coded severity of trauma patients. Thus, the bill has the potential to increase or decrease trauma center payments depending on the results of the severity ranking system. Additionally, 40% of trauma center funding is distributed based on trauma caseload Trauma Registry data. The bill requires the Trauma Registry data to be audited yearly. If the audit finds inaccurate data it may increase or decrease trauma center payments.

D. FISCAL COMMENTS:

Department of Health Fiscal Estimates

According to the Department of Health (DOH), there will be a fiscal impact to contract with an independent entity to provide contract management and conduct an annual audit of Trauma Registry data at each of the 21 trauma centers. It would cost at least $750,000 annually to contract with an independent entity to conduct a yearly onsite audit at each of the 21 trauma centers. This cost is based on the review of approximately 5,000 (10% of the estimated total trauma registry volume reported to the DOH Trauma Registry) trauma medical records. The average cost to conduct an audit is $100 an hour per medical record. A medical record coder can code/audit one medical record per hour at a total cost of $500,000. An additional $250,000 would be needed to cover an independent entity's personnel travel, expenses and for preparing and submitting reports for each trauma center to DOH.

According to DOH, an Operations and Management Consultant II would be needed to handle the request to negotiate the contract, ongoing contract management, and management of the independent entity. This position would also be responsible for collecting cost data and resource consumption data from each of the 21 trauma centers. A Computer System Analyst would be needed to develop and maintain the computerized algorithms for calculating the survival risk ratios (SRR) for each reported ICD-9 diagnosis code and subsequent determination of the ICD-9 Injury Severity Score (ICISS), resource utilization and cost ratios.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rule making authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to trauma services; amending s. 395.4001, F.S.; providing definitions; repealing s. 395.4035, F.S., to terminate the Trauma Services Trust Fund; amending s. 395.4036, F.S.; revising provisions relating to distribution of funds to trauma centers and use thereof; amending s. 395.404, F.S.; requiring an annual audit of Trauma Registry data; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 395.4001, Florida Statutes, is amended to read:

395.4001 Definitions.--As used in this part, the term:

(1) "Agency" means the Agency for Health Care Administration.

(2) "Charity care" or "uncompensated trauma care" means that portion of hospital charges reported to the agency for which there is no compensation, other than restricted or unrestricted revenues provided to a hospital by local governments or tax districts regardless of method of payment, for care provided to a patient whose family income for the 12 months preceding the determination is less than or equal to 200 percent of the federal poverty level, unless the amount of hospital charges due from the patient exceeds 25 percent of the annual family income. However, in no case shall the hospital charges for a patient whose family income exceeds four times the

federal poverty level for a family of four be considered charity.

(3) "Department" means the Department of Health.

(4) "Interfacility trauma transfer" means the transfer of a trauma victim between two facilities licensed under this chapter, pursuant to this part.

(5) "International Classification Injury Severity Score" means the statistical method for computing the severity of injury sustained by trauma patients. The International Classification Injury Severity Score shall be the methodology used by the department and trauma centers to report the severity of an injury.

(6) ~~(5)~~ "Level I trauma center" means a trauma center that:

(a) Has formal research and education programs for the enhancement of trauma care; is verified by the department to be in substantial compliance with Level I trauma center and pediatric trauma center standards; and has been approved by the department to operate as a Level I trauma center.

(b) Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.

(7) ~~(6)~~ "Level II trauma center" means a trauma center that:

(a) Is verified by the department to be in substantial compliance with Level II trauma center standards and has been

approved by the department to operate as a Level II trauma center.

(b) Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care.

(8) ~~(7)~~ "Pediatric trauma center" means a hospital that is verified by the department to be in substantial compliance with pediatric trauma center standards as established by rule of the department and has been approved by the department to operate as a pediatric trauma center.

(9) ~~(8)~~ "Provisional trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a provisional Level I trauma center, Level II trauma center, or pediatric trauma center.

(10) ~~(9)~~ "Trauma agency" means a department-approved agency established and operated by one or more counties, or a department-approved entity with which one or more counties contract, for the purpose of administering an inclusive regional trauma system.

(11) ~~(10)~~ "Trauma alert victim" means a person who has incurred a single or multisystem injury due to blunt or penetrating means or burns, who requires immediate medical intervention or treatment, and who meets one or more of the adult or pediatric scorecard criteria established by the department by rule.

(12) "Trauma caseload volume" means the number of trauma patients reported by individual trauma centers to the Trauma Registry and validated by the department.

(13) ~~(11)~~ "Trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center.

(14) "Trauma patient" means a person who has incurred a physical injury or wound caused by trauma and has accessed a trauma center.

(15) ~~(12)~~ "Trauma scorecard" means a statewide methodology adopted by the department by rule under which a person who has incurred a traumatic injury is graded as to the severity of his or her injuries or illness and which methodology is used as the basis for making destination decisions.

(16) ~~(13)~~ "Trauma transport protocol" means a document which describes the policies, processes, and procedures governing the dispatch of vehicles, the triage, prehospital transport, and interfacility trauma transfer of trauma victims.

(17) ~~(14)~~ "Trauma victim" means any person who has incurred a single or multisystem injury due to blunt or penetrating means or burns and who requires immediate medical intervention or treatment.

Section 2. Section 395.4035, Florida Statutes, is repealed.

Section 3. Subsection (1) of section 395.4036, Florida Statutes, is amended to read:

395.4036 Trauma payments.--

(1) Recognizing the Legislature's stated intent to provide financial support to the current verified trauma centers and to provide incentives for the establishment of additional trauma centers as part of a system of state-sponsored trauma centers, the department shall utilize funds collected under s. 318.18(15) ~~(14)~~ and deposited into the Administrative Trust Fund of the department to ensure the availability and accessibility of trauma services throughout the state as provided in this subsection.

(a) Twenty percent of the total funds collected under this subsection during the state fiscal year shall be distributed to verified trauma centers ~~located in a region~~ that have ~~has~~ a local funding contribution as of December 31. Distribution of funds under this paragraph shall be based on the department's audited Trauma Registry trauma caseload volume for the previous calendar year.

(b) Forty percent of the total funds collected under this subsection shall be distributed to verified trauma centers based on trauma caseload volume of the previous calendar year. The determination of caseload volume for distribution of funds under this paragraph shall be based on the department's audited Trauma Registry data.

(c) Forty percent of the total funds collected under this subsection shall be distributed to verified trauma centers based on severity of trauma patients. The determination of severity for distribution of funds under this paragraph shall be based on the department's audited Trauma Registry International

Classification Injury Severity Scores and other statistically valid and scientifically accepted methods of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by the department by rule, weighted based on the costs associated with and incurred by the trauma center in treating trauma patients. The weighting of scores shall be established by the department by rule ~~scores of 1-14 and 15 plus~~.

Funds deposited in the department's Administrative Trust Fund for verified trauma centers may be used to maximize the receipt of federal funds that may be available for such trauma centers. Notwithstanding this section and s. 318.14, distributions to trauma centers may be adjusted in a manner to ensure that total payments to trauma centers represent the same proportional allocation as set forth in this section and s. 318.14. For purposes of this section and s. 318.14, total funds distributed to trauma centers may include revenue from the Administrative Trust Fund and federal funds for which revenue from the Administrative Trust Fund is used to meet state or local matching requirements. ~~Trauma centers may request that their distributions from the Administrative Trust Fund be used as intergovernmental transfer funds in the Medicaid program.~~

Section 4. Paragraph (c) is added to subsection (1) of section 395.404, Florida Statutes, to read:

395.404 Review of trauma registry data; report to central registry; confidentiality and limited release.--

(1)

(c) An independent entity shall annually audit Trauma Registry data and submit the audit report to the department.

Section 5. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 715**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Grimsley offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 395.4001, Florida Statutes, is amended to read:

395.4001 Definitions.--As used in this part, the term:

(1) "Agency" means the Agency for Health Care Administration.

(2) "Charity care" or "uncompensated trauma care" means that portion of hospital charges reported to the agency for which there is no compensation, other than restricted or unrestricted revenues provided to a hospital by local governments or tax districts regardless of method of payment, for care provided to a patient whose family income for the 12 months preceding the determination is less than or equal to 200 percent of the federal poverty level, unless the amount of hospital charges due from the patient exceeds 25 percent of the annual family income. However, in no case shall the hospital charges for a patient whose family income exceeds four times the

federal poverty level for a family of four be considered charity.

(3) "Department" means the Department of Health.

(4) "Interfacility trauma transfer" means the transfer of a trauma victim between two facilities licensed under this chapter, pursuant to this part.

(5) "International Classification Injury Severity Score" means the statistical method for computing the severity of injury sustained by trauma patients. The International Classification Injury Severity Score shall be the methodology used by the department and trauma centers to report the severity of an injury.

(6) ~~(5)~~ "Level I trauma center" means a trauma center that:

(a) Has formal research and education programs for the enhancement of trauma care; is verified by the department to be in substantial compliance with Level I trauma center and pediatric trauma center standards; and has been approved by the department to operate as a Level I trauma center.

(b) Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.

(7) ~~(6)~~ "Level II trauma center" means a trauma center that:

(a) Is verified by the department to be in substantial compliance with Level II trauma center standards and has been approved by the department to operate as a Level II trauma center.

(b) Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care.

(8) "Local funding contribution" means local municipal, county or tax district funding exclusive of any patient specific funds received pursuant to ss. 154.301-154.316; private foundation funding; or public or private grant funding of at least $150,000 received by a hospital or health care system that operates a trauma center.

(9) ~~(7)~~ "Pediatric trauma center" means a hospital that is verified by the department to be in substantial compliance with pediatric trauma center standards as established by rule of the department and has been approved by the department to operate as a pediatric trauma center.

(10) ~~(8)~~ "Provisional trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a provisional Level I trauma center, Level II trauma center, or pediatric trauma center.

(11) ~~(9)~~ "Trauma agency" means a department-approved agency established and operated by one or more counties, or a department-approved entity with which one or more counties contract, for the purpose of administering an inclusive regional trauma system.

(12) ~~(10)~~ "Trauma alert victim" means a person who has incurred a single or multisystem injury due to blunt or penetrating means or burns, who requires immediate medical intervention or treatment, and who meets one or more of the

adult or pediatric scorecard criteria established by the department by rule.

(13) "Trauma caseload volume" means the number of trauma patients reported by individual trauma centers to the Trauma Registry and validated by the department.

(14) ~~(11)~~ "Trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center.

(15) "Trauma patient" means a person who has incurred a physical injury or wound caused by trauma and has accessed a trauma center.

(16) ~~(12)~~ "Trauma scorecard" means a statewide methodology adopted by the department by rule under which a person who has incurred a traumatic injury is graded as to the severity of his or her injuries or illness and which methodology is used as the basis for making destination decisions.

(17) ~~(13)~~ "Trauma transport protocol" means a document which describes the policies, processes, and procedures governing the dispatch of vehicles, the triage, prehospital transport, and interfacility trauma transfer of trauma victims.

(18) ~~(14)~~ "Trauma victim" means any person who has incurred a single or multisystem injury due to blunt or penetrating means or burns and who requires immediate medical intervention or treatment.

Section 2. Section 395.4035, Florida Statutes, is repealed.

Section 3. Subsection (1) of section 395.4036, Florida Statutes, is amended to read:

395.4036 Trauma payments.--

(1) Recognizing the Legislature's stated intent to provide financial support to the current verified trauma centers and to provide incentives for the establishment of additional trauma centers as part of a system of state-sponsored trauma centers, the department shall utilize funds collected under s. 318.18(15) ~~(14)~~ and deposited into the Administrative Trust Fund of the department to ensure the availability and accessibility of trauma services throughout the state as provided in this subsection.

(a) Twenty percent of the total funds collected under this subsection during the state fiscal year shall be distributed to verified trauma centers ~~located in a region~~ that have ~~has~~ a local funding contribution as of December 31. Distribution of funds under this paragraph shall be based on trauma caseload volume for the most recent calendar year available.

(b) Forty percent of the total funds collected under this subsection shall be distributed to verified trauma centers based on trauma caseload volume of the most recent ~~previous~~ calendar year available. The determination of caseload volume for distribution of funds under this paragraph shall be based on the department's Trauma Registry data.

(c) Forty percent of the total funds collected under this subsection shall be distributed to verified trauma centers based on severity of trauma patients for the most recent calendar year available. The determination of severity for distribution of funds under this paragraph shall be based on the department's Trauma Registry International Classification Injury Severity Scores or other statistically valid and scientifically accepted methods of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by the department by rule, weighted based on the costs associated with

and incurred by the trauma center in treating trauma patients. The weighting of scores shall be established by the department by rule ~~scores of 1-14 and 15 plus~~.

Funds deposited in the department's Administrative Trust Fund for verified trauma centers may be used to maximize the receipt of federal funds that may be available for such trauma centers. Notwithstanding this section and s. 318.14, distributions to trauma centers may be adjusted in a manner to ensure that total payments to trauma centers represent the same proportional allocation as set forth in this section and s. 318.14. For purposes of this section and s. 318.14, total funds distributed to trauma centers may include revenue from the Administrative Trust Fund and federal funds for which revenue from the Administrative Trust Fund is used to meet state or local matching requirements. ~~Trauma centers may request that their distributions from the Administrative Trust Fund be used as intergovernmental transfer funds in the Medicaid program.~~ Funds collected under ss. 318.14 and 318.18(15) and deposited in the Administrative Trust Fund of the department shall be distributed to trauma centers on a quarterly basis using the most recent calendar year data available. Such data shall not be used for more than four quarterly distributions, unless there are extenuating circumstances as determined by the department, in which case the most recent calendar year data available will continue to be used and as soon as the more recent data becomes available adjustments will be made accordingly.

Section 4. Section 395.65, Florida Statutes, is created to read:

395.65 Trauma center start-up.--There is established a trauma center start-up grant program.

(1) The Legislature recognizes the need for a statewide, cohesive, uniform and integrated trauma system, and the Legislature acknowledges that the state has been divided into trauma service areas. Each of the trauma service areas should have at least one trauma center; however some trauma service areas do not have a trauma center because of the significant up-front investment of capital incurred by hospitals to develop the physical space, equipment, and qualified personnel necessary to provide quality trauma services.

(2) An acute care general hospital that has submitted a letter of intent and an application to become a trauma center pursuant to s. 395.4025 may apply to the department for a start-up grant. The grant applicant must demonstrate that:

(a) There are currently no other trauma centers in the hospital's trauma service area as established under s. 395.402.

(b) There is not a trauma center within a 100-mile radius of the proposed trauma center.

(c) The hospital has received a local funding contribution as defined under s. 395.4001.

(d) The hospital has incurred start-up costs in excess of the amount of grant funding requested.

(e) The hospital is pursuing the establishment of a residency program in emergency medicine.

(3) Any hospital receiving start-up grant funding that does not become a provisional trauma center within 24-months after submitting an application to become a trauma center must forfeit any state grant funds received pursuant to this section.

Section 5. For the 2006-2007 fiscal year only, $500,000 is appropriated from the General Revenue Fund for deposit into the Administrative Trust Fund in the Department of Health for the purpose of providing trauma center start-up grants under s.

395.60. No one hospital may receive in excess of $500,000, start-up grant funding must be matched dollar for dollar with a local funding contribution, and start-up grant funding will only be provided to a hospital one-time.

Section 6. This act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Remove the entire title and insert:

A bill to be entitled

An act relating to trauma services; amending s. 395.4001, F.S.; providing definitions; repealing s. 395.4035, F.S., to terminate the Trauma Services Trust Fund; amending s. 395.4036, F.S.; revising provisions relating to distribution of funds to trauma centers and use thereof; providing grant funding for a trauma center in Tallahassee; providing an appropriation; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 859 Physician Assistants
SPONSOR(S): Baxley
TIED BILLS: **IDEN./SIM. BILLS:** SB 1690

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Health & Families Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

HB 859 requires a licensed physician assistant designated by the Council on Physician Assistants to be a member of a probable cause panel considering disciplinary action against a licensed physician assistant.

The bill also removes a requirement that a physician cosign the medical charts and records that are prepared by a physician assistant, if the supervising licensed physician is located on the business premises.

Identical language is added to the practice acts for allopathic and osteopathic physicians.

The bill does not appear to have a significant fiscal impact on state or local governments.

The bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote personal responsibility-The bill provides that a physician assistant who is under investigation by a probable cause panel will have a physician assistant sit on the probable cause panel. This provides physician assistants a voice in determining the disciplinary action of members of their profession.

B. EFFECT OF PROPOSED CHANGES:

The bill requires a probable cause panel considering disciplinary action against a licensed physician assistant to require that a licensed physician assistant designated by the Council on Physician Assistants be on the disciplinary panel, if one is available.

The bill removes the requirement that a physician cosign the medical charts and records prepared by a physician assistant, if the supervising licensed physician is located on the business premises.

Identical language is added to the practice acts for allopathic and osteopathic physicians.

PRESENT SITUATION

Currently, there are about 3,000 licensed physician assistants and 33,000 licensed allopathic and osteopathic physicians in Florida. Physician assistants practice under the indirect supervision of allopathic and osteopathic physicians. Physician assistants are governed under identical provisions within the practice act for medicine and osteopathic medicine respectively, ss. 458.347 and 459.022. F.S.

Council on Physician Assistants
The Council on Physician Assistants is created within the Department of Health and consists of five members: (3) doctors from the Board of Medicine, one of whom must supervise a physician assistant, (1) doctor from the Board of Osteopathic Medicine, and (1) licensed physician assistant appointed by the Secretary of the department. The Council on Physician Assistants may not adopt rules unless they are accepted and approved by the Board of Medicine and the Board of Osteopathic Medicine.

The Board of Medicine or the Board of Osteopathic Medicine may impose any of the penalties on physician assistants that are authorized in ss. 456.072 and 458.331(2) or 459.015(2), F.S.

Membership Requirements for Probable Cause Panels
Section 456.073(4), F.S. provides that a probable cause panel must be composed of at least two members; one or more of the members may be a former board member; one member must be one of the board's former or present consumer members, if one is available. Any probable cause panel must include a former or present professional board member with an active license for the profession they are representing.

Cosignature of Medical Records and Charts
Currently in rule, all tasks and procedures performed by a physician assistant must be documented in the appropriate medical record and later reviewed, signed, and dated by the supervising physician. According to the Board of Medicine, the cosigning of medical records and charts is the primary tool used by the board to determine whether a physician assistant is having duties appropriately delegated to them by a supervising physician and if the physician assistant is operating within their scope of practice.

C. SECTION DIRECTORY:

Section 1. Amends s. 458.331, F.S., to require that when a probable cause panel is considering disciplinary action against a physician assistant, the probable cause panel of the Board of Medicine must include a physician assistant that is recommended by the Council on Physician Assistants, unless one is not available,.
Section 2. Amends s. 458.347, F.S., to provide that medical charts and records do not require a cosignature by a licensed physician, if they are prepared by a physician assistant who is under the supervision of a licensed physician located on the business premises.
Section 3. Amends s. 459.015, F.S., to require that when a probable cause panel is considering disciplinary action against a physician assistant, the probable cause panel of the Board of Osteopathic Medicine must include a physician assistant that is recommended by the Council on Physician Assistants, unless one is not available.
Section 4. Amends s. 459.022, F.S., to provide that medical charts and records do not require a cosignature by a licensed physician, if they are prepared by a physician assistant who is under the supervision of a licensed physician located on the business premises.
Section 5. Provides that this bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None. (See "D. FISCAL COMMENTS.")

D. FISCAL COMMENTS:

According to the Department of Health, there will be some costs involved in having an additional person attend a probable cause panel meeting. The cost will not be significant.

The bill allows more efficient handling of medical records and charts by removing the requirement for physician cosignature that is not required of comparable health care practitioners. Advanced registered nurse practitioner's (ANRP's) perform services similar to that of a physician assistant, but are not required to have medical records or charts reviewed and cosigned by a supervising physician.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is needed to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, the bill does not define "business premises." This could be interpreted to mean that any location where the supervising physician sees patients, no matter how infrequently would be a "business premises."

Section 458.307(4), F.S., provides that no member of the Board of Medicine will participate or be part of a probable cause panel unless he or she has completed a disciplinary training program. Since the physician assistant is not an appointed member of a board, they would not be required to attend disciplinary training program. The disciplinary training program provides probable cause members the knowledge needed to determine the grounds for disciplinary action, changes in relevant statutes and rules, and any relevant judicial and administrative decisions.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to physician assistants; amending ss. 458.331 and 459.015, F.S.; placing a physician assistant on probable cause panels of the Board of Medicine and the Board of Osteopathic Medicine considering discipline of physician assistants; amending ss. 458.347 and 459.022, F.S.; authorizing the preparation of certain medical charts and records without the cosignature of a licensed physician; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (2) of section 458.331, Florida Statutes, is amended to read:

458.331 Grounds for disciplinary action; action by the board and department.--

(2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1). A probable cause panel considering disciplinary action against a physician assistant under s. 456.073 must include a licensed physician assistant designated by the Council on Physician Assistants unless a physician assistant is not available. In determining what action is appropriate, the board must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been

imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the physician. All costs associated with compliance with orders issued under this subsection are the obligation of the physician.

Section 2. Paragraph (g) is added to subsection (4) of section 458.347, Florida Statutes, to read:

458.347 Physician assistants.--

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.--

(g) The medical charts and records prepared by a physician assistant who is under the supervision of a licensed physician on the business premises do not require cosignature by the licensed physician.

Section 3. Subsection (2) of section 459.015, Florida Statutes, is amended to read:

459.015 Grounds for disciplinary action; action by the board and department.--

(2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1). A probable cause panel considering disciplinary action against a physician assistant under s. 456.073 must include a licensed physician assistant designated by the Council on Physician Assistants unless a physician assistant is not available. In determining what action is appropriate, the board must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been

imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the physician. All costs associated with compliance with orders issued under this subsection are the obligation of the physician.

Section 4. Paragraph (f) is added to subsection (4) of section 459.022, Florida Statutes, to read:

459.022 Physician assistants.--

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.--

(f) The medical charts and records prepared by a physician assistant who is under the supervision of a licensed physician on the business premises do not require cosignature by the licensed physician.

Section 5. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 859**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill:

Representative(s) Baxley offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (2) of section 458.331, Florida Statutes, is amended to read:

458.331 Grounds for disciplinary action; action by the board and department.--

(2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1). A probable cause panel considering disciplinary action against a physician assistant pursuant to s. 456.073 shall include one physician assistant holding an active Florida license to practice as a physician assistant who has been designated by the Council on Physician Assistants. The designated physician assistant shall only hear cases involving disciplinary action against physician assistants. If the designated physician

assistant is not available at the time the case is heard, the panel may consider and vote on the case in the absence of the designated physician assistant. The training requirement set forth in s. 456.307(4) does not apply to the designated physician assistant. Rulemaking as set forth in s. 456.073(4) is not required to implement this section. In determining what action is appropriate, the board must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the physician. All costs associated with compliance with orders issued under this subsection are the obligation of the physician.

Section 2. Subsection (2) of section 459.015, Florida Statutes, is amended to read:

459.015 Grounds for disciplinary action; action by the board and department.--

(2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1). A probable cause panel considering disciplinary action against a physician assistant pursuant to s. 456.073 shall include one physician assistant holding an active Florida license to practice as a physician assistant who has been designated by the Council on Physician Assistants. The designated physician assistant shall only hear cases involving disciplinary action against physician assistants. If the designated physician assistant is not available at the time the case is heard, the panel may consider and vote on the case in the absence of the

designated physician assistant. The training requirement set forth in s. 456.307(4) does not apply to the designated physician assistant. Rulemaking as set forth in s. 456.073(4) is not required to implement this section. In determining what action is appropriate, the board must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the physician. All costs associated with compliance with orders issued under this subsection are the obligation of the physician.

Section 3. This act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Remove the entire title and insert:

A bill to be entitled

An act relating to physician assistants; amending ss. 458.331 and 459.015, F.S.; placing a physician assistant on probable cause panels of the Board of Medicine and the Board of Osteopathic Medicine considering discipline of physician assistants; providing exceptions; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 881 Physician Licensure Requirements
SPONSOR(S): Flores
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Colleges & Universities Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

To be eligible for a license to practice medicine, medical doctors must complete an approved residency program. Residency is the period of clinical education in a medical specialty that follows graduation from medical school and prepares physicians for the independent practice of medicine.

HB 881 provides that in lieu of a residency program individuals may opt, with approval by the board of medicine, to complete a 2-year community-based internship at a hospital licensed in the state. If a doctor successfully completes the community-based internship, they meet the residency education requirement. The bill provides that the community-based internship must be "substantially equivalent" to the current residency program. The bill provides that if the community-based internship is provided in a hospital that is not licensed in the state, the department will impose a condition, limitation, or restriction on a license.

The community-based internship location and program must be approved by the board prior to an individual entering the internship. The bill provides the board the authority to adopt rules to implement the community-based internship, to include the implementation of fees to cover administrative costs. The bill provides the board of medicine the authority to determine by rule what is "substantially equivalent" to the current residency program and whether a medical doctor has successfully completed the community-based internship.

Fiscal Impact: According to the Department of Health, implementation of the bill will involve added costs for public hearings and the rulemaking authority, the exact cost is indeterminate.

The bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote personal responsibility-The bill allows individuals to work in the profession for which they were trained.

B. EFFECT OF PROPOSED CHANGES:

To be eligible for a license to practice medicine, medical doctors must complete an approved clinical residency program after graduation from medical school that prepares them for the independent practice of medicine.

The bill provides that in lieu of a residency program individuals may with approval by the board of medicine, complete a 2-year community-based internship at a hospital licensed in the state. The bill provides that the community-based internship must be "substantially equivalent" to the current residency program. The bill provides that if the community-based internship is provided in a hospital that is not licensed in the state, the department will impose a condition, limitation, or restriction on a license.

The community-based internship location and program must be approved by the board prior to entering the internship. The bill provides the board the authority to adopt rules to implement the community-based internship, and implement fees to cover administrative costs. The bill provides the board of medicine the authority to determine by rule what is "substantially equivalent" to the current residency program and whether a medical doctor has successfully completed the community-based internship.

PRESENT SITUATION

Accredited by the Council for Graduate Medical Education (ACGME) and Residency Programs

The Accreditation Council for Graduate Medical Education (ACGME) is responsible for the Accreditation of post-MD (residency) medical training programs within the United States. Accreditation is accomplished through a peer review process and is based upon established standards and guidelines.[1] ACGME accredits nearly 7,800 residency education programs.

To gain and maintain accreditation, residency programs are expected to comply with the Accreditation Standards for their discipline and adhere to a set of Institutional Requirements. Compliance with the ACGME's standards are measured through periodic reviews of all programs.

Educational Commission for Foreign Medical Graduates (ECFMG) Program Certification

The Educational Commission for Foreign Medical Graduates (ECFMG), through its program of certification, assesses whether international medical graduates are ready to enter residency or fellowship programs in the United States that are accredited by the Accreditation Council for Graduate Medical Education (ACGME).[2]

ECFMG and its organizational members define an international medical graduate as a physician who received his/her basic medical degree or qualification from a medical school located outside the United States and Canada. ECFMG Certification assures directors of ACGME-accredited residency and

[1]Accreditation Council for Graduate Medical Education. *About ACGME.* http://www.acgme.org/acWebsite/home/home.asp (February 12, 2006).
[2] ECFMG Information Booklet. *Frequently Asked Questions.* http://www.ecfmg.org/2006ib/ibfaq.html (February 12, 2006)

fellowship programs, and the people of the United States, that international medical graduates have met minimum standards of eligibility required to enter such programs. International medical graduates(IMG), who were formally referred to as foreign trained medical graduates, must have had at least four credit years (or academic years for which credit has been given toward completion of the medical curriculum) in attendance at a medical school listed in the International Medical Education Directory (IMED).

In general, an international medical graduate is defined as a physician whose basic medical degree or qualification was conferred by a medical school located outside the United States, Canada, and Puerto Rico.

United States Medical Licensing Examination (USMLE) Examination and Credentialing

To be eligible for certification by ECFMG, international medical graduates must meet an examination and medical education credential requirement. The examination requirement requires applicants to pass Step 1 and both parts of Step 2 of the United States Medical Licensing Examination (USMLE). Step 2 of the exam has two separately administered components: the Clinical Knowledge (CK) component and the Clinical Skills (CS) component.[3] The medical education credential requirement requires applicants to provide their medical education credentials, which includes their final medical diploma and final medical school transcript. ECFMG certification is one of the eligibility requirements to take Step 3 of the USMLE examination.

Examination Requirements that were formally available to International Medical Graduates

The 1-day ECFMG medicine examination, the 2-day Visa Qualifying Examination, the Part I and Part II examinations of the National Board of Medical Examiners (NBME), and Day 1 and Day 2 of the Foreign Medical Graduate Examination in the Medical Sciences are no longer administered, but a passing performance on any of those medical science examinations is accepted for ECFMG certification

The 3-day Federation Licensing Examination (FLEX) is accepted for ECFMG certification if taken prior to June 1985 with a score of 75 or higher on each of the 3 days of a single administration.

While foreign national physicians may meet the medical science examination requirement for ECFMG certification based on the former 1-day ECFMG examination that was last administered in February 1984, or the FLEX examination taken prior to June 1985, these examinations are not currently recognized by the US Secretary of Health and Human Services as meeting the medical science examination requirement to obtain a visa to enter the United States.

Fifth Pathway Program provided by the Liaison Committee on Medical Education (LCME)

The Liaison Committee on Medical Education (LCME) is the nationally recognized accrediting authority for medical education programs leading to the M.D. degree in U.S. and Canadian medical schools. The LCME is sponsored by the Association of American Medical Colleges and the American Medical Association. Accreditation by the Liaison Committee on Medical Education (LCME) is required for schools to receive federal grants for medical education and to participate in federal loan programs.[4]

The LCME also accredits the Fifth Pathway Program that provides an alternative for clinical residency. Currently, only two medical schools provide the Fifth Pathway Program. They are located in New York and Puerto Rico.[5]

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[3] Ibid.
[4] Liaison Committee on Medical Education. Overview: Accreditation and the LCME. http://www.lcme.org/ (February 12, 2006).
[5] Accreditation Council for Graduate Medical Education. Section I: Graduate Medical Education Useful Information. http://www.acgme.org/acWebsite/GME_info/gme_sect1Policy.asp (February 13, 2006).

The Fifth Pathway Program is an academic year of supervised clinical education provided in a medical school accredited by the Liaison Committee on Medical Education (LCME). It is available to persons who meet all of the following conditions:

- Have completed, an accredited US college or university, undergraduate premedical work of the quality acceptable for matriculation in an accredited US medical school;
- Have studied medicine in a medical school located outside the United States, Puerto Rico, and Canada that is listed in the World Directory of Medical Schools, published by the World Health Organization;
- Have completed all of the formal requirements of the non-US medical school except internship and/or social service. (Those who have completed all of these requirements, including internship and/or social service, are not eligible for a fifth pathway program.)

Students who have completed the academic curriculum in residence at a non-US medical school and who meet the above conditions may be offered the opportunity to substitute, an academic year of supervised clinical training provided in a medical school accredited by the LCME, for an internship and/or social service required by a non-US medical school.

Before beginning the supervised clinical training, students must pass an examination acceptable to the sponsoring medical school.

Physicians who have a Fifth Pathway Certificate and have passed Steps I and II of the United States Medical Licensing Examination (USMLE) are eligible for appointment to a residency program. They must also meet requirements established by the state medical board in the state where the residency program is located and must be accepted for appointment by the director of the residency program. Any medical school accredited by the LCME can provide Fifth Pathway education.

Statutory Provisions for Foreign Trained Physicians

Restricted License

Section 458.312, F.S., expired on December 31, 2000. This section provided an exemption to foreign trained medical graduates that allowed them to apply to take Step III of the USMLE examination if they successfully complete a two-year period of direct and indirect supervised training as a restricted licensee. Applicants for the restricted license had to have at least legally practiced medicine for 5 years in the county where they received their medical degree, received ECFMG certification, and been a resident of Florida since July 1, 1996.

Under this program, the applicant was required to practice for the first year under the direct supervision of a licensed medical doctor, approved by the Board of Medicine. For the second year, they were required to practice under indirect supervision in a community service setting that served the indigent population.

If the foreign trained medical graduate completed the two-year period of supervised training and successfully passed part III of the USMLE examination they were eligible for full licensure.

Graduates of a Medical School may work in Hospitals

Section 458.345, F.S., provides that a person who is at least 21 years of age, has not committed any act or offense within or outside the state that would constitute grounds for disciplinary action, and is a graduate of a medical school or college is eligible to work in a hospital as a house physician, resident physician, assistant resident physician, intern, or fellow in fellowship training. Registration under this provision expires every two years.

According to the Department of Health, currently, there are 307 individuals licensed as a house physician.

C. SECTION DIRECTORY:

Section 1. Amends s. 458.311, F.S., to provide a definition for "community-based internship," and provide an option to licensure applicants to compete an internship; to require the Department of Health to develop procedures and an approval process relating to the completion of the internship requirements; to authorize the department to adopt rules to implement the internship requirements and set fees to cover costs; to allow the department to impose conditions, limitations, or restrictions of a license for an individual who completes a community-based internship.
Sections 2 through 6 amend ss. 458.313, 458.316, 458.3165, 458.317, and 458.347, F.S., to correct cross-references.
Section 7. Provides that the bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See "D. FISCAL COMMENTS."

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The community-based internship will allow medical doctors who have practiced medicine in their native countries and who are older than the traditional medical student, the opportunity to practice medicine in their community. Medical doctors from other states who do not receive a slot in a traditional residency program may seek licensure in Florida by successfully completing a community-based internship.

D. FISCAL COMMENTS:

Implementing a two-year community-based internship will involve added costs for public hearings and the rulemaking process by both the Department of Health and the Board of Medicine. Board review of these training programs to determine whether they are "substantially similar" to approved residency programs will increase meeting, travel, and administrative costs. The costs are indeterminate, but may be substantial if Florida faces a strong demand for community-based internships.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the rulemaking authority to the Department of Health and the Board of Medicine to implement the community-based internship requirements.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill sponsor has prepared a strike-all amendment to address these issues.

DRAFTING ISSUES:
According to the Department of Health, the bill is not intended to change the need to pass the ECFMG examination; however, the way it is drafted may cause unintended consequences and may cause controversy as to whether it allows applicants under the Fifth Pathway option to sit for Part III of the USMLE examination.

Due to the fact that only two schools offer the Fifth Pathway, controversy over this issue would probably be minimal.

OTHER COMMENTS:
According to DOH, the department and the Board of Medicine do not have the resources or the expertise to evaluate and manage postgraduate training in the form of "community-based internships" in Florida. The department and the Board of Medicine would be tasked with investigating and credentialing special training programs in Florida hospitals and with evaluating whether the training is substantially equivalent to Florida's residency programs. This task is new to the department and Board of Medicine regulatory mission and will require additional time, resources and staff. The number of programs that would seek approval is unknown. The proposed program may attract national attention for those who have been unable to find a residency as well as those who have taken and failed to successfully complete a residency.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to physician licensure requirements; amending s. 458.311, F.S.; providing a definition; providing an option for certain applicants for physician licensure to complete an internship; authorizing the Department of Health to develop procedures relating to completion of the internship; requiring board approval of internships; authorizing the board to adopt rules to implement internship requirements, including fees to cover costs; revising the requirement of the department to impose conditions, limitations, or restrictions on a license; amending ss. 458.313, 458.316, 458.3165, 458.317, and 458.347, F.S.; correcting cross-references; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (2) through (8) of section 458.311, Florida Statutes, are renumbered as subsections (3) through (9), respectively, present subsections (5) and (7) are amended, and a new subsection (2) is added to that section, to read:

458.311 Licensure by examination; requirements; fees.--

(2)(a) As used in this section, the term "community-based internship" means a program approved by the board in which a graduate from a foreign medical school obtains required postgraduate clinical experience at a hospital licensed in this state.

(b) Notwithstanding sub-subparagraphs(1)(f)1.c., 2.c., and 3.c. and paragraph (4)(d), except for passing part II of the National Board of Medical Examiners examination or the Educational Commission for Foreign Medical Graduates examination equivalent as referred to in paragraph (4)(d), the department may develop procedures for an applicant for licensure to meet postgraduate training requirements by completion of a 2-year community-based internship at a hospital licensed in this state. The training provided in the community-based internship shall be substantially similar, as defined by board rule, to the training provided in an approved residency as provided in sub-subparagraph (1)(f)1.c., sub-subparagraph (1)(f)2.c., or sub-subparagraph (1)(f)3.c. In order for the community-based internship to meet the requirements of this subsection, the community-based internship must be approved by the board prior to the applicant's entering into the community-based internship. The applicant shall not be licensed under this subsection unless the board finds that the applicant has successfully completed the community-based internship. The board may adopt rules to implement this subsection, including rules setting fees, which may not exceed the actual costs of administering this subsection.

(6) ~~(5)~~ The board may not certify to the department for licensure any applicant who is under investigation in another jurisdiction for an offense which would constitute a violation of this chapter until such investigation is completed. Upon completion of the investigation, the provisions of s. 458.331 shall apply. Furthermore, the department may not issue an

unrestricted license to any individual who has committed any act or offense in any jurisdiction which would constitute the basis for disciplining a physician pursuant to s. 458.331. When the board finds that an individual has committed an act or offense in any jurisdiction which would constitute the basis for disciplining a physician pursuant to s. 458.331, then the board may enter an order imposing one or more of the terms set forth in subsection (9) ~~(8)~~.

(8) ~~(7)~~ Upon certification by the board, the department shall impose conditions, limitations, or restrictions on a license if the applicant is on probation in another jurisdiction for an act which would constitute a violation of this chapter or if the community-based internship requirement provided in subsection (2) was complied with at a hospital that is not licensed in this state.

Section 2. Paragraph (a) of subsection (1) of section 458.313, Florida Statutes, is amended to read:

458.313 Licensure by endorsement; requirements; fees.--

(1) The department shall issue a license by endorsement to any applicant who, upon applying to the department on forms furnished by the department and remitting a fee set by the board not to exceed $500, the board certifies:

(a) Has met the qualifications for licensure in s. 458.311(1)(b)-(g) or in s. 458.311(1)(b)-(e) and (g) and (4) ~~(3)~~;

Section 3. Subsection (1) of section 458.316, Florida Statutes, is amended to read:

458.316 Public health certificate.--

(1) Any person desiring to obtain a public health certificate shall submit an application fee not to exceed $300 and shall demonstrate to the board that he or she is a graduate of an accredited medical school and holds a master of public health degree or is board eligible or certified in public health or preventive medicine, or is licensed to practice medicine without restriction in another jurisdiction in the United States and holds a master of public health degree or is board eligible or certified in public health or preventive medicine, and shall meet the requirements in s. 458.311(1)(a)-(g) and (6) ~~(5)~~.

Section 4. Section 458.3165, Florida Statutes, is amended to read:

458.3165 Public psychiatry certificate.--The board shall issue a public psychiatry certificate to an individual who remits an application fee not to exceed $300, as set by the board, who is a board-certified psychiatrist, who is licensed to practice medicine without restriction in another state, and who meets the requirements in s. 458.311(1)(a)-(g) and (6) ~~(5)~~. A recipient of a public psychiatry certificate may use the certificate to work at any public mental health facility or program funded in part or entirely by state funds.

(1) Such certificate shall:

(a) Authorize the holder to practice only in a public mental health facility or program funded in part or entirely by state funds.

(b) Be issued and renewable biennially if the secretary of the Department of Health and the chair of the department of psychiatry at one of the public medical schools or the chair of

the department of psychiatry at the accredited medical school at the University of Miami recommend in writing that the certificate be issued or renewed.

(c) Automatically expire if the holder's relationship with a public mental health facility or program expires.

(d) Not be issued to a person who has been adjudged unqualified or guilty of any of the prohibited acts in this chapter.

(2) The board may take disciplinary action against a certificateholder for noncompliance with any part of this section or for any reason for which a regular licensee may be subject to discipline.

Section 5. Paragraph (a) of subsection (1) of section 458.317, Florida Statutes, is amended to read:

458.317 Limited licenses.--

(1)(a) Any person desiring to obtain a limited license shall:

1. Submit to the board, with an application and fee not to exceed $300, an affidavit stating that he or she has been licensed to practice medicine in any jurisdiction in the United States for at least 10 years and intends to practice only pursuant to the restrictions of a limited license granted pursuant to this section. However, a physician who is not fully retired in all jurisdictions may use a limited license only for noncompensated practice. If the person applying for a limited license submits a notarized statement from the employing agency or institution stating that he or she will not receive compensation for any service involving the practice of medicine,

the application fee and all licensure fees shall be waived. However, any person who receives a waiver of fees for a limited license shall pay such fees if the person receives compensation for the practice of medicine.

2. Meet the requirements in s. 458.311(1)(b)-(g) and (6) ~~(5)~~. If the applicant graduated from medical school prior to 1946, the board or its appropriate committee may accept military medical training or medical experience as a substitute for the approved 1-year residency requirement in s. 458.311(1)(f).

Nothing herein limits in any way any policy by the board, otherwise authorized by law, to grant licenses to physicians duly licensed in other states under conditions less restrictive than the requirements of this section. Notwithstanding the other provisions of this section, the board may refuse to authorize a physician otherwise qualified to practice in the employ of any agency or institution otherwise qualified if the agency or institution has caused or permitted violations of the provisions of this chapter which it knew or should have known were occurring.

Section 6. Paragraph (b) of subsection (7) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.--

(7) PHYSICIAN ASSISTANT LICENSURE.--

(b)1. Notwithstanding subparagraph (a)2. and sub-subparagraph (a)3.a., the department shall examine each applicant who the Board of Medicine certifies:

a. Has completed the application form and remitted a nonrefundable application fee not to exceed $500 and an examination fee not to exceed $300, plus the actual cost to the department to provide the examination. The examination fee is refundable if the applicant is found to be ineligible to take the examination. The department shall not require the applicant to pass a separate practical component of the examination. For examinations given after July 1, 1998, competencies measured through practical examinations shall be incorporated into the written examination through a multiple-choice format. The department shall translate the examination into the native language of any applicant who requests and agrees to pay all costs of such translation, provided that the translation request is filed with the board office no later than 9 months before the scheduled examination and the applicant remits translation fees as specified by the department no later than 6 months before the scheduled examination, and provided that the applicant demonstrates to the department the ability to communicate orally in basic English. If the applicant is unable to pay translation costs, the applicant may take the next available examination in English if the applicant submits a request in writing by the application deadline and if the applicant is otherwise eligible under this section. To demonstrate the ability to communicate orally in basic English, a passing score or grade is required, as determined by the department or organization that developed it, on the test for spoken English (TSE) by the Educational Testing Service (ETS), the test of English as a foreign language (TOEFL) by ETS, a high school or college level English course,

or the English examination for citizenship, Bureau of Citizenship and Immigration Services. A notarized copy of an Educational Commission for Foreign Medical Graduates (ECFMG) certificate may also be used to demonstrate the ability to communicate in basic English; and

b.(I) Is an unlicensed physician who graduated from a foreign medical school listed with the World Health Organization who has not previously taken and failed the examination of the National Commission on Certification of Physician Assistants and who has been certified by the Board of Medicine as having met the requirements for licensure as a medical doctor by examination as set forth in s. 458.311(1), (4) ~~(3)~~, (5) ~~(4)~~, and (6) ~~(5)~~, with the exception that the applicant is not required to have completed an approved residency of at least 1 year and the applicant is not required to have passed the licensing examination specified under s. 458.311 or hold a valid, active certificate issued by the Educational Commission for Foreign Medical Graduates; was eligible and made initial application for certification as a physician assistant in this state between July 1, 1990, and June 30, 1991; and was a resident of this state on July 1, 1990, or was licensed or certified in any state in the United States as a physician assistant on July 1, 1990; or

(II) Completed all coursework requirements of the Master of Medical Science Physician Assistant Program offered through the Florida College of Physician's Assistants prior to its closure in August of 1996. Prior to taking the examination, such applicant must successfully complete any clinical rotations that

were not completed under such program prior to its termination and any additional clinical rotations with an appropriate physician assistant preceptor, not to exceed 6 months, that are determined necessary by the council. The boards shall determine, based on recommendations from the council, the facilities under which such incomplete or additional clinical rotations may be completed and shall also determine what constitutes successful completion thereof, provided such requirements are comparable to those established by accredited physician assistant programs. This sub-sub-subparagraph is repealed July 1, 2001.

2. The department may grant temporary licensure to an applicant who meets the requirements of subparagraph 1. Between meetings of the council, the department may grant temporary licensure to practice based on the completion of all temporary licensure requirements. All such administratively issued licenses shall be reviewed and acted on at the next regular meeting of the council. A temporary license expires 30 days after receipt and notice of scores to the licenseholder from the first available examination specified in subparagraph 1. following licensure by the department. An applicant who fails the proficiency examination is no longer temporarily licensed, but may apply for a one-time extension of temporary licensure after reapplying for the next available examination. Extended licensure shall expire upon failure of the licenseholder to sit for the next available examination or upon receipt and notice of scores to the licenseholder from such examination.

3. Notwithstanding any other provision of law, the examination specified pursuant to subparagraph 1. shall be

administered by the department only five times. Applicants certified by the board for examination shall receive at least 6 months' notice of eligibility prior to the administration of the initial examination. Subsequent examinations shall be administered at 1-year intervals following the reporting of the scores of the first and subsequent examinations. For the purposes of this paragraph, the department may develop, contract for the development of, purchase, or approve an examination that adequately measures an applicant's ability to practice with reasonable skill and safety. The minimum passing score on the examination shall be established by the department, with the advice of the board. Those applicants failing to pass that examination or any subsequent examination shall receive notice of the administration of the next examination with the notice of scores following such examination. Any applicant who passes the examination and meets the requirements of this section shall be licensed as a physician assistant with all rights defined thereby.

Section 7. This act shall take effect July 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7045 PCB GO 06-16 OGSR Supplemental Rebate Agreements
SPONSOR(S): Governmental Operations Committee, Rivera
TIED BILLS: None **IDEN./SIM. BILLS:** SB 516

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Governmental Operations Committee	5 Y, 0 N	Williamson	Williamson
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) State Administration Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

The Open Government Sunset Review Act requires the Legislature to review each public records and each public meetings exemption five years after enactment. If the Legislature does not reenact the exemption, it automatically repeals on October 2nd of the fifth year after enactment.

The bill reenacts the public records exemption relating to supplemental rebate agreements. It narrows the exemption by removing the public records exemption for trade secrets. The bill reenacts the public meetings exemption for the Medicaid Pharmaceutical and Therapeutics Committee. In addition, it requires that a record be made of each portion of an exempt meeting. The exemptions will repeal on October 2, 2006, if this bill does not become law.

This bill may have a fiscal impact on state government. It does not appear to have a fiscal impact on local governments.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – The bill narrows the public records exemption thereby increasing public access to government information. The bill requires the Medicaid Pharmaceutical and Therapeutics Committee to make a record of each portion of an exempt meeting.

B. EFFECT OF PROPOSED CHANGES:

Background

The 2001 Florida Legislature significantly expanded its efforts to control pharmaceutical costs in the state's Medicaid program by enacting a program called the preferred drug list (PDL).[1] Under this law, Medicaid prescribing practitioners are required to prescribe the medications on the PDL, or must obtain prior authorization from the Agency for Health Care Administration (AHCA) to prescribe a medication not on the PDL, in order for Medicaid to pay for the prescription.

In order for a drug manufacturer to have its medications considered for inclusion on the PDL, it must agree to provide the state both federally mandated rebates and state-mandated supplemental rebates. Since rebate negotiations involve disclosure by pharmaceutical manufacturers of proprietary information regarding the elements of their wholesale pricing, federal law prohibits disclosure of information received by Medicaid agencies from manufacturers that discloses identities of manufacturers or wholesalers or the prices charged by these manufacturers or wholesalers.[2] The federal prohibition applies to the U.S. Secretary of the Department of Health and Human Services, the U.S. Secretary of Veterans Affairs, or a state agency or contractor.

To address the federal confidentiality requirements and to ensure the use of this pricing information for negotiating state supplemental rebate agreements, the 2001 Legislature enacted a public records and public meetings exemption related to rebate negotiations.[3] Trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates with respect to supplemental rebate negotiations are confidential and exempt[4] from public records requirements.

According to Senate interim project report 2006-219, the state supplemental rebate negotiation process has been facilitated by this exemption and has been successful in benefiting the people of Florida. Since its implementation in 2002, the PDL program has generated over $262 million in state supplemental rebates, with $292 million in additional costs savings projected for Fiscal Year 2005-2006, a significant portion of which will be derived from supplemental rebate negotiations.

Current law also provides a public meetings exemption applicable in limited circumstances. Portions of meetings of the Medicaid Pharmaceutical and Therapeutics Committee are exempt from public meetings requirements if the aforementioned confidential and exempt records are discussed.[5]

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[1] Chapter 2001-104, L.O.F.
[2] 42 U.S.C. 1396r 8
[3] Chapter 2001 216, L.O.F.; codified in s. 409.91196, F.S.
[4] There is a difference between records that are exempt from public records requirements and those that are *confidential* and exempt. If the Legislature makes a record confidential and exempt, such record cannot be released by an agency to anyone other than to the persons or entities designated in the statute. *See* Attorney General Opinion 85-62. If a record is simply made exempt from disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances. *See Williams v. City of Minneola*, 575 So.2d 683, 687 (Fla. 5th DCA), review denied, 589 So.2d 289 (Fla. 1991).
[5] Section 409.91196(2), F.S.

Pursuant to the Open Government Sunset Review Act,[6] the exemption will repeal on October 2, 2006, unless reenacted by the Legislature.[7] House staff reviewed the public records and public meetings exemption pursuant to the Open Government Sunset Review Act and determined that, with modification, the exemption meets the requirements for reenactment.[8] Based on AHCA's survey response, it appeared that the public records exemption for trade secrets was unnecessary because AHCA stated that rebate agreements and supplemental rebate amounts were trade secrets for purposes of the exemption. Such information is protected under the current public records exemption.

Effect of Bill

The bill removes the repeal date, thereby reenacting the public records and public meetings exemptions. It narrows the public records exemption by removing the exemption for trade secrets.

The bill requires the Medicaid Pharmaceutical and Therapeutics Committee, which is created within AHCA,[9] to make a record of each portion of an exempt meeting. The record must include the time of commencement and termination, all discussions and proceedings, the names of all persons present at any time, and the names of all persons speaking. The record of the exempt portion of a meeting is a public record; however, the rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebate included in the record is confidential and exempt from public disclosure because of the public records exemption already afforded AHCA.[10]

Finally, the bill makes editorial changes and removes superfluous language.

C. SECTION DIRECTORY:

Section 1. - Amends s. 409.91196, F.S., to remove the repeal date.

Section 2. - Provides an effective date of October 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill does not create, modify, amend, or eliminate a state revenue source.

2. Expenditures:

   [*See* FISCAL COMMENTS.]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   The bill does not create, modify, amend, or eliminate a local revenue source.

2. Expenditures:

   The bill does not create, modify, amend, or eliminate local expenditures.

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[6] Section 119.15, F.S.
[7] Section 409.91196(3), F.S.
[8] Staff surveyed and interviewed AHCA staff.
[9] Section 409.91195, F.S.
[10] *See* s. 409.91196(1), F.S.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill requires the Medicaid Pharmaceutical and Therapeutics Committee, which is a part of AHCA, to maintain a record of exempt portions of meetings. This could create a negative fiscal impact; however, the committee already hires a court reporter to keep a record of the open portion of the meeting. As such, additional expenditures should be avoided.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Open Government Sunset Review Act

The Open Government Sunset Review Act sets forth a legislative review process for newly created or substantially amended public records or public meetings exemptions. It requires an automatic repeal of the exemption on October 2nd of the fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.

The Act provides that a public records or public meetings exemption may be created or maintained only if it serves an identifiable public purpose, and may be no broader than is necessary to meet one of the following purposes:

- Allowing the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protecting sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety. However, only the identity of an individual may be exempted under this provision; or,
- Protecting trade or business secrets.

If, and only if, in reenacting an exemption that will repeal, the exemption is expanded (essentially creating a new exemption), then a public necessity statement and a two-thirds vote for passage are required because of the requirements of Art. 1, s. 24(c), Florida Constitution. If the exemption is reenacted with grammatical or stylistic changes that do not expand the exemption, if the exemption is narrowed, or if an exception to the exemption is created (e.g., allowing another agency access to the confidential or exempt records), then a public necessity statement and a two-thirds vote for passage are not required.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

None.

A bill to be entitled

An act relating to a review under the Open Government Sunset Review Act regarding supplemental rebate agreements; amending s. 409.91196, F.S., which provides an exemption from public records requirements for the rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebate held by the Agency for Health Care Administration relative to a preferred drug list established by the agency and an exemption from public meetings requirements for that portion of a meeting of the Medicaid Pharmaceutical and Therapeutics Committee at which such rebate amounts, percent of rebates, manufacturer's pricing, and supplemental rebates are discussed; making editorial changes; removing superfluous language; requiring that a record of an exempt portion of a meeting be made and maintained; removing the scheduled repeal of the exemption; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 409.91196, Florida Statutes, is amended to read:

409.91196 Supplemental rebate agreements; public ~~confidentiality of~~ records and public meetings exemption.--

(1) The ~~Trade secrets,~~ rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebate held by ~~rebates which are contained in records of~~ the Agency for Health Care Administration under s. 409.912(39)(a)7. ~~and its agents with~~

~~respect to supplemental rebate negotiations and which are prepared pursuant to a supplemental rebate agreement under s. 409.912(40)(a)7.~~ are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(2) That portion of a meeting ~~Those portions of meetings~~ of the Medicaid Pharmaceutical and Therapeutics Committee at which the ~~trade secrets,~~ rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebate ~~rebates~~ are discussed is ~~disclosed for discussion or negotiation of a supplemental rebate agreement under s. 409.912(40)(a)7. are~~ exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution. A record shall be made of each exempt portion of a meeting. Such record must include the times of commencement and termination, all discussions and proceedings, the names of all persons present at any time, and the names of all persons speaking. No exempt portion of a meeting may be held off the record.

~~(3) Subsections (1) and (2) are subject to the Open Government Sunset Review Act of 1995 in accordance with s. 119.15, and shall stand repealed on October 2, 2006, unless reviewed and saved from repeal through reenactment by the Legislature.~~

Section 2. This act shall take effect October 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCR 06-02 Licensure of Health Care Providers
SPONSOR(S): Health Care Regulation Committee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Health Care Regulation Committee		Bell AJB	Mitchell
1)			
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

The Licensure of Health Care Providers Proposed Committee Bill (PCB) eliminates unnecessary duplication and variation of licensure requirements by health care providers licensed by the Agency for Health Care Administration (AHCA). The bill defines common terminology and consolidates core licensure requirements in newly created part II of chapter 408, F.S. The organization of core, uniform standards is similar to the regulatory scheme for health care practitioners by the Department of Health.

Standard minimum licensure requirements consolidated in the bill include: timeframes for the license application processing, two-year renewal cycle, definition of change of ownership, background screening, notice of exclusion from Medicare or Medicaid, notice of closure, inactive license, records retention, right of inspection, inspection reports, unlicensed activity, administrative fines, moratoriums, license denial, emergency suspension, and revocation.

The bill lists the facilities affected by the bill.

The effective date of the bill is October 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill consolidates licensure standards and regulations of health care facilities into core licensure statutes. The bill streamlines current regulation and decreases unnecessary variations.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

The licensure statutes for various health care providers regulated by AHCA contain duplication and variation of certain basic licensing standards. These standards include the application process, changes of ownership, licensure categories, background screenings, changes of administrator, right of inspection, inspection reports, unlicensed activity, administrative fines, moratoriums, and license denial and revocation. The majority of licenses are required to be renewed annually, although some programs call for biennial licensure. Each of these regulatory statutes has evolved independently and as such there is variation in the definitions of similar requirements. Licensure processing occurs within the broad requirements of licensure under the Administrative Procedures Act, s. 120.60, F.S., and many unique requirements within each specify authorizing statutes or rules.

Effect of Bill

The bill creates part II of chapter 408, F.S., by establishing a set of minimum core licensing requirements for all health care providers licensed by the Agency for Health Care Administration to eliminate unnecessary duplication and variation of licensure requirements among providers. This organization of core, uniform standards is similar to the regulatory scheme for health care practitioners within chapter 456, F.S., by the Department of Health. Common definitions of basic standards serve to eliminate confusion for operators of multiple provider types and streamline the licensure process. The bill creates streamlined and consistent licensing requirements for all providers regulated by AHCA, by standardizing terminology in basic licensure requirements.

The health care licensing programs subject to part II of Chapter 408, F.S. include:

- Drug Free Workplace Laboratories, as provided under ss. 112.0455 and 440.102;
- Birth Centers, as provided under chapter 383, F.S.;
- Abortion Clinics, as provided under chapter 390, F.S.;
- Crisis Stabilization Units, as provided under parts I and IV of chapter 394, F.S.;
- Short Term Residential Treatment Units, as provided under parts I and IV of chapter 394, F.S.; Residential Treatment Facilities, as provided under part IV of chapter 394, F.S.;
- Residential Treatment Centers for Children and Adolescents, as provided under part IV of chapter 394;
- Hospitals, as provided under part I of chapter 395, F.S.;
- Ambulatory Surgical Centers, as provided under part I of chapter 395, F.S.;
- Mobile Surgical Facilities, as provided under part I of chapter 395, F.S.;
- Private Review Agents, as provided under part I of chapter 395, F.S.;
- Health Care Risk Managers, as provided under part I of chapter 395, F.S.;
- Nursing Homes, as provided under part II of chapter 400, F.S.;
- Assisted Living Facilities, as provided under part III of chapter 400, F.S.;
- Home Health Agencies, as provided under part IV of chapter 400, F.S.;
- Nurse Registries, as provided under part IV of chapter 400, F.S.;

- Companion Services or Homemaker Services Providers, as provided under part IV of chapter 400, F.S.;
- Adult Day Care Centers, as provided under part V of chapter 400, F.S.;
- Hospices, as provided under part VI of chapter 400, F.S.;
- Adult Family-Care Homes, as provided under part VII of chapter 400, F.S.;
- Homes for Special Services as provided under part VIII of chapter 400, F.S.;
- Transitional Living Facilities, as provided under part VIII of chapter 400, F.S.;
- Prescribed Pediatric Extended Care Centers, as provided under part IX of chapter 400, F.S.;
- Home Medical Equipment Providers, as provided under part X of chapter 400, F.S.;
- Intermediate Care Facilities for the Developmentally Disabled, as provided under part XI of chapter 400, F.S.;
- Health Care Services Pools, as provided under part XII of chapter 400, F.S.;
- Health Care Clinics, as provided under part XIII of chapter 400, F.S.;
- Clinical Laboratories, as provided under part I of chapter 483, F.S.;
- Multiphasic Health Testing Centers, as provided under part II of chapter 483, F.S.; and
- Certification of Organizations Engaged in the Practice Of Cadaveric Organ and Tissue Procurement, Certification of Organ Procurement Organizations, Tissue Banks and Eye Banks as provided under chapter 765, F.S.

The bill creates licensing and regulatory standards for all of the above programs.

Licensure Requirements
The bill provides that it is unlawful to provide or offer services that require a license without first obtaining a license. Applicants must submit the appropriate application with license fee to the Agency for Health Care Administration (AHCA). The license fee cannot exceed the actual cost of regulation pursuant to part II of chapter 408. F.S., authorizing statutes, and administrative rules. Licensure fees may be adjusted annually based on the change in the consumer price index within existing maximum levels if increases are necessary to support the actual cost of regulation.

Inspection Fees
The bill provides for the assessment of inspection fees if required by authorizing statute and a fee assessment for license re-issuance due to a reported change by the provider.

Licensure Renewals
The bill mandates the timeframes for initial, renewal, and change of ownership application submission; the timeframe for AHCA review and approval or denial of applications; and the timeframe for applicant submission of omitted application information. These timeframes provide more specific direction than the broad licensing requirements of s. 120.60, F.S. The duration of a license is typically two years, but conditions of licensure category can shorten that period, such as the issuance of a provisional license. Change of ownership responsibilities of the transferor and transferee are specified in the bill.

Licensure Categories
The bill details the conditions for issuing a standard, provisional, or inactive license.

Background Check Requirements
Federal Bureau of Investigation (FBI) and Florida Department of Law Enforcement (FDLE) background screening is required for administrators, individual owners, and financial officers. A person with controlling interest is subject to background screening when there is reason to believe such person has a disqualifying offense. Notice of change of a person required to undergo background screening must be reported to AHCA, pursuant to the specific authorizing statute and rule requirements. New persons who are subject to the screening requirements must comply with background screening requirements; however, they may be employed pending FBI screening results if the state level (FDLE) screening is clear.

AHCA Right of Entry & Administrative Actions
The Agency for Health Care Administration (AHCA) has the right of entry and inspection of premises to determine compliance with part II of Chapter 408, F.S., authorizing statutes, and rules. AHCA may not enter into a premise, which AHCA believes is operating without a valid license unless permission is granted by the owner or a warrant is first obtained. The bill provides for administrative actions against unlicensed providers. The bill allows the agency to impose administrative fines, a moratorium on admissions, license denial, emergency suspension or revocation, or seek injunctive relief for regulatory violations affecting resident health, safety or welfare.

C. SECTION DIRECTORY:

Section 1. – Creates Part I of Chapter 408, F.S., consisting of sections 408.031, 408.032, 408.033, 408.034, 408.035, 408.036, 408.0361, 408.037, 408.038, 408.039, 408.040, 408.041, 408.042, 408.043, 408.044, 408.045, 408.0455, 408.05, 408.061, 408.062, 408.063, 408.07, 408.08, 408.09, 408.10, 408.15, 408.16, 408.18, 408.185, 408.20, 408.301, 408.302, 408.40, 408.50, 408.70, 408.7056, 408.7057, and 408.7071, F.S., entitled "Health Facility and Services Planning."

Section 2. – Creates Part II of Chapter 408, F.S., consisting of sections 408.801, 408.802, 408.803, 408.804, 408.805, 408.806, 408.807, 408.808, 408.809, 408.810, 408.811, 408.812, 408.813, 408.814, 408.815, 408.816, 408.817, 408.818, 408.819, 408.820, and 408.831, F.S., entitled "Health Care Licensing: General Provisions."

Section 3. – Creates Part III of Chapter 408, F.S., consisting of sections 408.90, 408.901, 408.902, 408.903, 408.904, 408.905, 408.906, 408.907, 408.908, and 408.909, F.S., entitled "Health Insurance Access."

Section 4. – Creates Part IV of Chapter 408, F.S., consisting of sections 408.911, 408.913, 408.914, 408.915, 408.916, 408.917, and 408.918, F.S., entitled "Health and Human Services Eligibility Access System."

Section 5. – Creates sections 408.801 – 408.820, F.S., to consolidate licensing requirements for facilities and services licensed by AHCA.

Section 6. – Amends s. 400.801, F.S., to redefine "home for special services" to mean a site licensed by AHCA prior to January 1, 2006.

Section 7. – Amends s. 408.831, F.S. to authorize AHCA to deny any application, or suspend or revoke any license when a licensee subject to part II of chapter 408, F.S., shares a common controlling interest with the applicant and has failed to pay all outstanding monies due to AHCA.

Section 8. - Specifies that the provisions of part II of chapter 408, F.S., prevail over provider authorizing statutes in case of a conflict.

Section 9. - The bill authorizes AHCA to double current annual licensure fees to provide for biennial licensure.

Section 10. – Directs the Division of Statutory Revision of the Office of Legislative Services to assist, substantive committees of the Senate and House of Representatives, in the preparation of draft legislation to conform the Florida Statutes and any legislation enacted during 2006 to the act.

Section 11. - The bill authorizes AHCA to issue any license for less than two years by charging a prorated licensure fee and specifying a different renewal date between October 1, 2006 and September 30, 2008. This will allow for staggering of expiration dates as providers change from annual to biennial licensure.

Section 12. - The effective date of the bill is October 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

In future years, licensure fees may be adjusted annually based on the change in the consumer price index within existing maximum levels if increases are necessary to support the actual cost of regulation.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill authorizes rule making authority for the Agency for Health Care Administration to carry out provisions of the core licensing provisions. Some licensure requirements that are currently in rule will no longer be necessary if core licensure standards are implemented.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to the licensure of health care providers; creating pts. I, II, III, and IV of ch. 408, F.S.; creating s. 408.801, F.S.; providing a short title; providing legislative findings and purpose; creating s. 408.802, F.S.; providing applicability; creating s. 408.803, F.S.; providing definitions; creating s. 408.804, F.S.; requiring providers to have and display a license; providing limitations; creating s. 408.805, F.S.; establishing license fees and conditions for assessment thereof; providing a method for calculating annual adjustment of fees; providing for inspection fees; providing that fees are nonrefundable; creating s. 408.806, F.S.; providing a license application process; requiring specified information to be included on the application; requiring payment of late fees under certain circumstances; requiring inspections; providing an exception; authorizing the Agency for Health Care Administration to establish procedures and rules for electronic transmission of required information; creating s. 408.807, F.S.; providing procedures for change of ownership; requiring the transferor to notify the agency in writing within a specified time period; providing for duties and liability of the transferor; providing for maintenance of certain records; creating s. 408.808, F.S.; providing license categories and requirements therefor; creating s. 408.809, F.S.; requiring background screening of specified employees; providing for submission of proof of compliance, under certain circumstances; providing

conditions for granting provisional and standard licenses; providing an exception to screening requirements; creating s. 408.810, F.S.; providing minimum licensure requirements; providing procedures for discontinuance of operation and surrender of license; requiring forwarding of client records; requiring publication of a notice of discontinuance of operation of a provider; providing for statewide toll-free telephone numbers for reporting complaints and abusive, neglectful, and exploitative practices; requiring proof of legal right to occupy property, proof of insurance, and proof of financial viability, under certain circumstances; requiring disclosure of information relating to financial instability; providing a penalty; prohibiting the agency from licensing a health care provider that does not have a certificate of need or an exemption; creating s. 408.811, F.S.; providing for inspections and investigations to determine compliance; providing that inspection reports are public records; requiring retention of records for a specified period of time; creating s. 408.812, F.S.; prohibiting certain unlicensed activity by a provider; requiring unlicensed providers to cease activity; providing penalties; requiring reporting of unlicensed providers; creating s. 408.813, F.S.; authorizing the agency to impose administrative fines; creating s. 408.814, F.S.; providing conditions for the agency to impose a moratorium or emergency suspension on a provider; requiring notice; creating s. 408.815, F.S.; providing grounds for denial or revocation of a license or change-

of-ownership application; providing conditions to continue operation; exempting renewal applications from provisions requiring the agency to approve or deny an application within a specified period of time, under certain circumstances; creating s. 408.816, F.S.; authorizing the agency to institute injunction proceedings, under certain circumstances; creating s. 408.817, F.S.; providing basis for review of administrative proceedings challenging agency licensure enforcement action; creating s. 408.818, F.S.; requiring fees and fines related to health care licensing to be deposited into the Health Care Trust Fund; creating s. 408.819, F.S.; authorizing the agency to adopt rules; providing a timeframe for compliance; creating s. 408.820, F.S.; providing exemptions from specified requirements of pt. II of ch. 408, F.S.; amending s. 400.801, F.S.; providing that the definition of homes for special services applies to sites licensed by the agency after a certain date; amending s. 408.831, F.S.; revising provisions relating to agency action to deny, suspend, or revoke a license, registration, certificate, or application; conforming cross-references; providing for priority of application in case of conflict; authorizing the agency to adjust annual licensure fees to provide biennial licensure fees; requesting interim assistance of the Division of Statutory Revision to prepare conforming legislation for the 2007 Regular Session; authorizing the agency to issue licenses for less than a specified time period and providing conditions therefor; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Part I of chapter 408, Florida Statutes, consisting of sections 408.031, 408.032, 408.033, 408.034, 408.035, 408.036, 408.0361, 408.037, 408.038, 408.039, 408.040, 408.041, 408.042, 408.043, 408.044, 408.045, 408.0455, 408.05, 408.061, 408.062, 408.063, 408.07, 408.08, 408.09, 408.10, 408.15, 408.16, 408.18, 408.185, 408.20, 408.301, 408.302, 408.40, 408.50, 408.70, 408.7056, 408.7057, and 408.7071, Florida Statutes, is created and entitled "Health Facility and Services Planning."

Section 2. Part II of chapter 408, Florida Statutes, consisting of sections 408.801, 408.802, 408.803, 408.804, 408.805, 408.806, 408.807, 408.808, 408.809, 408.810, 408.811, 408.812, 408.813, 408.814, 408.815, 408.816, 408.817, 408.818, 408.819, 408.820, and 408.831, Florida Statutes, is created and entitled "Health Care Licensing: General Provisions."

Section 3. Part III of chapter 408, Florida Statutes, consisting of sections 408.90, 408.901, 408.902, 408.903, 408.904, 408.905, 408.906, 408.907, 408.908, and 408.909, Florida Statutes, is created and entitled "Health Insurance Access."

Section 4. Part IV of chapter 408, Florida Statutes, consisting of sections 408.911, 408.913, 408.914, 408.915, 408.916, 408.917, and 408.918, Florida Statutes, is created and entitled "Health and Human Services Eligibility Access System."

Section 5. Sections 408.801, 408.802, 408.803, 408.804, 408.805, 408.806, 408.807, 408.808, 408.809, 408.810, 408.811, 408.812, 408.813, 408.814, 408.815, 408.816, 408.817, 408.818,

408.819, and 408.820, Florida Statutes, are created to read:

408.801 Short title; purpose.--

(1) This part may be cited as the "Health Care Licensing Procedures Act."

(2) The Legislature finds that there is unnecessary duplication and variation in the requirements for licensure by the agency. It is the intent of the Legislature to provide a streamlined and consistent set of basic licensing requirements for all such providers in order to minimize confusion, standardize terminology, and include issues that are otherwise not adequately addressed in the Florida Statutes pertaining to specific providers.

408.802 Applicability.--The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 440, 483, and 765:

(1) Laboratories authorized to perform testing under the Drug-Free Workplace Act, as provided under ss. 112.0455 and 440.102.

(2) Birth centers, as provided under chapter 383.

(3) Abortion clinics, as provided under chapter 390.

(4) Crisis stabilization units, as provided under parts I and IV of chapter 394.

(5) Short-term residential treatment facilities, as provided under parts I and IV of chapter 394.

(6) Residential treatment facilities, as provided under part IV of chapter 394.

(7) Residential treatment centers for children and

adolescents, as provided under part IV of chapter 394.

(8) Hospitals, as provided under part I of chapter 395.

(9) Ambulatory surgical centers, as provided under part I of chapter 395.

(10) Mobile surgical facilities, as provided under part I of chapter 395.

(11) Private review agents, as provided under part I of chapter 395.

(12) Health care risk managers, as provided under part I of chapter 395.

(13) Nursing homes, as provided under part II of chapter 400.

(14) Assisted living facilities, as provided under part III of chapter 400.

(15) Home health agencies, as provided under part IV of chapter 400.

(16) Nurse registries, as provided under part IV of chapter 400.

(17) Companion services or homemaker services providers, as provided under part IV of chapter 400.

(18) Adult day care centers, as provided under part V of chapter 400.

(19) Hospices, as provided under part VI of chapter 400.

(20) Adult family-care homes, as provided under part VII of chapter 400.

(21) Homes for special services, as provided under part VIII of chapter 400.

(22) Transitional living facilities, as provided under part VIII of chapter 400.

(23) Prescribed pediatric extended care centers, as provided under part IX of chapter 400.

(24) Home medical equipment providers, as provided under part X of chapter 400.

(25) Intermediate care facilities for persons with developmental disabilities, as provided under part XI of chapter 400.

(26) Health care services pools, as provided under part XII of chapter 400.

(27) Health care clinics, as provided under part XIII of chapter 400.

(28) Clinical laboratories, as provided under part I of chapter 483.

(29) Multiphasic health testing centers, as provided under part II of chapter 483.

(30) Organ and tissue procurement agencies, as provided under chapter 765.

408.803 Definitions.--As used in this part, the term:

(1) "Agency" means the Agency for Health Care Administration, which is the licensing agency under this part.

(2) "Applicant" means an individual, corporation, partnership, firm, association, or governmental entity that submits an application for a license to the agency.

(3) "Authorizing statute" means the statute authorizing the licensed operation of a provider listed in s. 408.802 and includes chapters 112, 383, 390, 394, 395, 400, 440, 483, and 765.

(4) "Certification" means certification as a Medicare or Medicaid provider of the services that require licensure, or

certification pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA).

(5) "Change of ownership" means an event in which the licensee changes to a different legal entity or in which 45 percent or more of the ownership, voting shares, or controlling interest in a corporation whose shares are not publicly traded on a recognized stock exchange is transferred or assigned, including the final transfer or assignment of multiple transfers or assignments over a 2-year period that cumulatively total 45 percent or greater. A change solely in the management company or board of directors is not a change of ownership.

(6) "Client" means any person receiving services from a provider listed in s. 408.802.

(7) "Controlling interest" means:

(a) The applicant or licensee;

(b) A person or entity that serves as an officer of, is on the board of directors of, or has a 5-percent or greater ownership interest in the applicant or licensee; or

(c) A person or entity that serves as an officer of, is on the board of directors of, or has a 5-percent or greater ownership interest in the management company or other entity, related or unrelated, with which the applicant or licensee contracts to manage the provider.

The term does not include a voluntary board member.

(8) "License" means any permit, registration, certificate, or license issued by the agency.

(9) "Licensee" means an individual, corporation, partnership, firm, association, or governmental entity that is

issued a permit, registration, certificate, or license by the agency. The licensee is legally responsible for all aspects of the provider operation.

(10) "Moratorium" means a prohibition on the acceptance of new clients.

(11) "Provider" means any activity, service, agency, or facility regulated by the agency and listed in s. 408.802.

(12) "Services that require licensure" means those services, including residential services, that require a valid license before those services may be provided in accordance with authorizing statutes and agency rules.

(13) "Voluntary board member" means a board member of a not-for-profit corporation or organization who serves solely in a voluntary capacity, does not receive any remuneration for his or her services on the board of directors, and has no financial interest in the corporation or organization. The agency shall recognize a person as a voluntary board member following submission of a statement to the agency by the board member and the not-for-profit corporation or organization that affirms that the board member conforms to this definition. The statement affirming the status of the board member must be submitted to the agency on a form provided by the agency.

408.804 License required; display.--

(1) It is unlawful to provide services that require licensure, or operate or maintain a provider that offers or provides services that require licensure, without first obtaining from the agency a license authorizing the provision of such services or the operation or maintenance of such provider.

(2) A license must be displayed in a conspicuous place

readily visible to clients who enter at the address that appears on the license and is valid only in the hands of the licensee to whom it is issued and may not be sold, assigned, or otherwise transferred, voluntarily or involuntarily. The license is valid only for the licensee, provider, and location for which the license is issued.

408.805 Fees required; adjustments.--Unless otherwise limited by authorizing statutes, license fees must be reasonably calculated by the agency to cover its costs in carrying out its responsibilities under this part, authorizing statutes, and applicable rules, including the cost of licensure, inspection, and regulation of providers.

(1) Licensure fees shall be adjusted to provide for biennial licensure under agency rules.

(2) The agency shall annually adjust licensure fees, including fees paid per bed, by not more than the change in the Consumer Price Index based on the 12 months immediately preceding the increase.

(3) The agency may, by rule, adjust licensure fees to cover the cost of administering this part, authorizing statutes, and applicable rules.

(4) An inspection fee must be paid as required in authorizing statutes.

(5) Fees are nonrefundable.

(6) When a change is reported that requires issuance of a license, a fee may be assessed. The fee must be based on the actual cost of processing and issuing the license.

(7) A fee may be charged to a licensee requesting a duplicate license. The fee may not exceed the actual cost of

duplication and postage.

(8) Total fees collected may not exceed the cost of administering this part, authorizing statutes, and applicable rules.

408.806 License application process.--

(1) An application for licensure must be made to the agency on forms furnished by the agency, submitted under oath, and accompanied by the appropriate fee in order to be accepted and considered timely. The application must contain information required by authorizing statutes and applicable rules and must include:

(a) The name, address, and social security number of the applicant and each controlling interest if the applicant or controlling interest is an individual.

(b) The name, address, and federal employer identification number or taxpayer identification number of the applicant and each controlling interest if the applicant or controlling interest is not an individual.

(c) The name by which the provider is to be known.

(d) The total number of beds or capacity requested, as applicable.

(e) The name of the person or persons under whose management or supervision the provider will operate and the name of the administrator, if required.

(f) If the applicant offers continuing care agreements as defined in chapter 651, proof shall be furnished that the applicant has obtained a certificate of authority as required for operation under chapter 651.

(g) Other information, including satisfactory inspection

results, that the agency finds necessary to determine the ability of the applicant to carry out its responsibilities under this part, authorizing statutes, and applicable rules.

(2)(a) The applicant for a renewal license must submit an application that must be received by the agency at least 60 days prior to the expiration of the current license.

(b) The applicant for initial licensure due to a change of ownership must submit an application that must be received by the agency at least 60 days prior to the date of change of ownership.

(c) For any other application or request, the applicant must submit an application or request that must be received by the agency at least 60 days prior to the requested effective date, unless otherwise specified in authorizing statutes or applicable rules.

(d) The agency shall notify the licensee by mail or electronically at least 90 days prior to the expiration of a license that a renewal license is necessary to continue operation. The failure to timely submit an application and license fee shall result in a late fee charged to the licensee by the agency in an amount equal to 50 percent of the licensure fee, but the aggregate amount of the fine may not exceed $5,000. If an application is received after the required filing date and exhibits a hand-canceled postmark obtained from a United States post office dated on or before the required filing date, no fine will be levied.

(3)(a) Upon receipt of an application for a license, the agency shall examine the application and, within 30 days after receipt, notify the applicant in writing of any apparent errors or omissions and request any additional information required.

(b) Requested information omitted from an application for licensure, license renewal, or change of ownership, other than an inspection, must be filed with the agency within 21 days after the agency's request for omitted information or the application shall be deemed incomplete and shall be withdrawn from further consideration and the fees shall be forfeited.

(c) Within 60 days after the receipt of a complete application, the agency shall approve or deny the application.

(4)(a) Licensees subject to the provisions of this part shall be issued biennial licenses unless conditions of the license category specify a shorter license period.

(b) Each license issued shall indicate the name of the licensee, the type of provider or service that the licensee is required or authorized to operate or offer, the date the license is effective, the expiration date of the license, the maximum capacity of the licensed premises, if applicable, and any other information required or deemed necessary by the agency.

(5) In accordance with authorizing statutes and applicable rules, proof of compliance with s. 408.810 must be submitted with an application for licensure.

(6) The agency may not issue an initial license to a health care provider subject to the certificate-of-need provisions in part I of this chapter if the licensee has not been issued a certificate of need or certificate-of-need exemption, when applicable. Failure to apply for the renewal of a license prior to the expiration date renders the license void.

(7)(a) An applicant must demonstrate compliance with the requirements in this part, authorizing statutes, and applicable rules during an inspection pursuant to s. 408.811, as required by

authorizing statutes.

(b) An initial inspection is not required for companion services or homemaker services providers, as provided under part IV of chapter 400, or for health care services pools, as provided under part XII of chapter 400.

(c) If an inspection is required by the authorizing statute for a license application other than an initial application, the inspection must be unannounced. This paragraph does not apply to inspections required pursuant to ss. 383.324, 395.0161(4), and 483.061(2).

(d) If a provider is not available when an inspection is attempted, the application shall be denied.

(8) The agency may establish procedures for the electronic notification and submission of required information, including, but not limited to:

(a) Licensure applications.

(b) Required signatures.

(c) Payment of fees.

(d) Notarization of applications.

Requirements for electronic submission of any documents required by this part or authorizing statutes may be established by rule.

408.807 Change of ownership.--Whenever a change of ownership occurs:

(1) The transferor shall notify the agency in writing at least 60 days before the anticipated date of the change of ownership.

(2) The transferee shall make application to the agency for a license within the timeframes required in s. 408.806.

(3) The transferor shall be responsible and liable for:

(a) The lawful operation of the provider and the welfare of the clients served until the date the transferee is licensed by the agency.

(b) Any and all penalties imposed against the transferor for violations occurring before the date of change of ownership.

(4) Any restriction on licensure, including a conditional license existing at the time of a change of ownership, shall remain in effect until removed by the agency.

(5) The transferee shall maintain records of the transferor as required in this part, authorizing statutes, and applicable rules, including:

(a) All client records.

(b) Inspection reports.

(c) All records required to be maintained pursuant to s. 409.913, if applicable.

408.808 License categories.--

(1) STANDARD LICENSE.--A standard license may be issued to an applicant at the time of initial licensure, license renewal, or change of ownership. A standard license shall be issued when the applicant is in compliance with all statutory requirements and agency rules. Unless sooner revoked, a standard license expires 2 years after the date of issue.

(2) PROVISIONAL LICENSE.--A provisional license may be issued to an applicant pursuant to s. 408.809(3). An applicant against whom a proceeding denying or revoking a license is pending at the time of license renewal may be issued a provisional license effective until final action not subject to further appeal.

(3) INACTIVE LICENSE.--An inactive license may be issued to a health care provider subject to the certificate-of-need provisions in part I of this chapter when the provider is currently licensed, does not have a provisional license, and will be temporarily unable to provide services but is reasonably expected to resume services within 12 months. Such designation may be made for a period not to exceed 12 months but may be renewed by the agency for up to 12 additional months upon demonstration by the licensee of the provider's progress toward reopening. A request by a licensee for an inactive license or to extend the previously approved inactive period must be submitted to the agency and must include a written justification for the inactive license with the beginning and ending dates of inactivity specified, a plan for the transfer of any clients to other providers, and the appropriate licensure fees. The agency may not accept a request that is submitted after initiating closure, after any suspension of service, or after notifying clients of closure or suspension of service, unless the action is a result of a natural disaster. Upon agency approval, the provider shall notify clients of any necessary discharge or transfer as required by authorizing statutes or applicable rules. The beginning of the inactive license period is the date the provider ceases operations. The end of the inactive license period shall become the license expiration date. All licensure fees must be current, must be paid in full, and may be prorated. Reactivation of an inactive license requires the approval of a renewal application, including payment of licensure fees and agency inspections indicating compliance with all requirements of this part, authorizing statutes, and applicable rules.

(4) OTHER LICENSES.--Other types of license categories may be issued pursuant to authorizing statutes or applicable rules.

408.809 Background screening; prohibited offenses.--

(1) Level 2 background screening pursuant to chapter 435 must be conducted through the agency on each of the following persons, who shall be considered an employee for the purposes of conducting screening under chapter 435:

(a) The licensee, if an individual.

(b) The administrator or a similarly titled person who is responsible for the day-to-day operation of the provider.

(c) The financial officer or similarly titled individual who is responsible for the financial operation of the licensee or provider.

(d) Any person who is a controlling interest if the agency has reason to believe that such person has been convicted of any offense prohibited by s. 435.04. For each controlling interest who has been convicted of any such offense, the licensee shall submit to the agency a description and explanation of the conviction at the time of license application.

(2) Proof of compliance with level 2 screening standards submitted within the previous 5 years to meet any provider or professional licensure requirements of the agency, the Department of Health, the Agency for Persons with Disabilities, or the Department of Children and Family Services satisfies the requirements of this section, provided that such proof is accompanied, under penalty of perjury, by an affidavit of compliance with the provisions of chapter 435 using forms provided by the agency. Proof of compliance with the background screening requirements of the Department of Financial Services

submitted within the previous 5 years for an applicant for a certificate of authority to operate a continuing care retirement community under chapter 651 satisfies the Department of Law Enforcement and Federal Bureau of Investigation portions of a level 2 background check.

(3) A provisional license may be granted to an applicant when each individual required by this section to undergo background screening has met the standards for the Department of Law Enforcement background check but the agency has not yet received background screening results from the Federal Bureau of Investigation. A standard license may be granted to the licensee upon the agency's receipt of a report of the results of the Federal Bureau of Investigation background screening for each individual required by this section to undergo background screening that confirms that all standards have been met or upon the granting of an exemption from disqualification by the agency as set forth in chapter 435.

(4) When a person is newly employed in a capacity that requires screening under this section, the licensee must notify the agency of the change within the time period specified in the authorizing statute or rules and must submit to the agency information necessary to conduct level 2 screening or provide evidence of compliance with background screening requirements of this section. The person may serve in his or her capacity pending the agency's receipt of the report from the Federal Bureau of Investigation if he or she has met the standards for the Department of Law Enforcement background check. However, the person may not continue to serve in his or her capacity if the report indicates any violation of background screening standards

unless an exemption from disqualification has been granted by the agency as set forth in chapter 435.

(5) Background screening is not required to obtain a certificate of exemption issued under s. 483.106.

408.810 Minimum licensure requirements.--In addition to the licensure requirements specified in this part, authorizing statutes, and applicable rules, each applicant and licensee must comply with the requirements of this section in order to obtain and maintain a license.

(1) An applicant for licensure must comply with the background screening requirements of s. 408.809.

(2) An applicant for licensure must provide a description and explanation of any exclusions, suspensions, or terminations of the applicant from the Medicare, Medicaid, or federal Clinical Laboratory Improvement Amendment (CLIA) programs.

(3) Unless otherwise specified in this part, authorizing statutes, or applicable rules, any information required to be reported to the agency must be submitted within 21 calendar days after the report period or effective date of the information.

(4) Whenever a licensee discontinues operation of a provider:

(a) The licensee must inform the agency not less than 30 days prior to the discontinuance of operation and inform clients of such discontinuance as required by authorizing statutes. Immediately upon discontinuance of operation by a provider, the licensee shall surrender the license to the agency and the license shall be canceled.

(b) The licensee shall remain responsible for retaining and appropriately distributing all records within the timeframes

prescribed in authorizing statutes and applicable rules. In addition, the licensee or, in the event of death or dissolution of a licensee, the estate or agent of the licensee shall:

1. Make arrangements to forward records for each client to one of the following, based upon the client's choice: the client or the client's legal representative, the client's attending physician, or the health care provider where the client currently receives services; or

2. Cause a notice to be published in the newspaper of greatest general circulation in the county in which the provider was located that advises clients of the discontinuance of the provider operation. The notice must inform clients that they may obtain copies of their records and specify the name, address, and telephone number of the person from whom the copies of records may be obtained. The notice must appear at least once a week for 4 consecutive weeks.

(5)(a) On or before the first day services are provided to a client, a licensee must inform the client and his or her immediate family or representative, if appropriate, of the right to report:

1. Complaints. The statewide toll-free telephone number for reporting complaints to the agency must be provided to clients in a manner that is clearly legible and must include the words: "To report a complaint regarding the services you receive, please call toll-free (phone number)."

2. Abusive, neglectful, or exploitative practices. The statewide toll-free telephone number for the central abuse hotline must be provided to clients in a manner that is clearly legible and must include the words: "To report abuse, neglect, or

exploitation, please call toll-free (phone number)." The agency shall publish a minimum of a 90-day advance notice of a change in the toll-free telephone numbers.

(b) Each licensee shall establish appropriate policies and procedures for providing such notice to clients.

(6) An applicant must provide the agency with proof of the applicant's legal right to occupy the property before a license may be issued. Proof may include, but need not be limited to, copies of warranty deeds, lease or rental agreements, contracts for deeds, quitclaim deeds, or other such documentation.

(7) If proof of insurance is required by the authorizing statute, that insurance must be in compliance with chapter 624, chapter 626, chapter 627, or chapter 628 and with agency rules.

(8) Upon application for initial licensure or change of ownership licensure, the applicant shall furnish satisfactory proof of the applicant's financial ability to operate in accordance with the requirements of this part, authorizing statutes, and applicable rules. The agency shall establish standards for this purpose, including information concerning the applicant's controlling interests. The agency shall also establish documentation requirements, to be completed by each applicant, that show anticipated provider revenues and expenditures, the basis for financing the anticipated cash-flow requirements of the provider, and an applicant's access to contingency financing. A current certificate of authority, pursuant to chapter 651, may be provided as proof of financial ability to operate. The agency may require a licensee to provide proof of financial ability to operate at any time if there is evidence of financial instability, including, but not limited to,

unpaid expenses necessary for the basic operations of the provider.

(9) A controlling interest may not withhold from the agency any evidence of financial instability, including, but not limited to, checks returned due to insufficient funds, delinquent accounts, nonpayment of withholding taxes, unpaid utility expenses, nonpayment for essential services, or adverse court action concerning the financial viability of the provider or any other provider licensed under this part that is under the control of the controlling interest. Any person who violates this subsection commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continuing violation is a separate offense.

(10) The agency may not issue a license to a health care provider subject to the certificate-of-need provisions in part I of this chapter if the health care provider has not been issued a certificate of need or an exemption. Upon initial licensure of any such provider, the authorization contained in the certificate of need shall be considered fully implemented and merged into the license and shall have no force and effect upon termination of the license for any reason.

408.811 Right of inspection; copies; inspection reports.--

(1) An authorized officer or employee of the agency may make or cause to be made any inspection or investigation deemed necessary by the agency to determine the state of compliance with this part, authorizing statutes, and applicable rules. The right of inspection extends to any business that the agency has reason to believe is being operated as a provider without a license, but inspection of any business suspected of being operated without

the appropriate license may not be made without the permission of the owner or person in charge unless a warrant is first obtained from a circuit court. Any application for a license issued under this part, authorizing statutes, or applicable rules constitutes permission for an appropriate inspection to verify the information submitted on or in connection with the application.

(a) All inspections shall be unannounced, except as specified in s. 408.806.

(b) Inspections for relicensure shall be conducted biennially unless otherwise specified by authorizing statutes or applicable rules.

(2) Inspections conducted in conjunction with certification may be accepted in lieu of a complete licensure inspection. However, a licensure inspection may also be conducted to review any licensure requirements that are not also requirements for certification.

(3) The agency shall have access to and the licensee shall provide copies of all provider records required during an inspection at no cost to the agency.

(4)(a) Each licensee shall maintain as public information, available upon request, records of all inspection reports pertaining to that provider that have been filed by the agency unless those reports are exempt from or contain information that is exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution or is otherwise made confidential by law. Effective October 1, 2006, copies of such reports shall be retained in the records of the provider for at least 3 years following the date the reports are filed and issued, regardless of a change of ownership.

(b) A licensee shall, upon the request of any person who has completed a written application with intent to be admitted by such provider, any person who is a client of such provider, or any relative, spouse, or guardian of any such person, furnish to the requester a copy of the last inspection report pertaining to the licensed provider that was issued by the agency or by an accrediting organization if such report is used in lieu of a licensure inspection.

408.812 Unlicensed activity.--

(1) A person or entity may not offer or advertise services that require licensure as defined by this part, authorizing statutes, or applicable rules to the public without obtaining a valid license from the agency. A licenseholder may not advertise or hold out to the public that he or she holds a license for other than that for which he or she actually holds the license.

(2) The operation or maintenance of an unlicensed provider or the performance of any services that require licensure without proper licensure is a violation of this part and authorizing statutes. Unlicensed activity constitutes harm that materially affects the health, safety, and welfare of clients. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the unlicensed provider or the performance of any services in violation of this part and authorizing statutes, until compliance with this part, authorizing statutes, and agency rules has been demonstrated to the satisfaction of the agency.

(3) It is unlawful for any person or entity to own, operate, or maintain an unlicensed provider. If after receiving

notification from the agency, such person or entity fails to cease operation and apply for a license under this part and authorizing statutes, the person or entity shall be subject to penalties as prescribed by authorizing statutes and applicable rules. Each day of continued operation is a separate offense.

(4) Any person or entity that fails to cease operation after agency notification may be fined $1,000 for each day of noncompliance.

(5) When a controlling interest or licensee has an interest in more than one provider and fails to license a provider rendering services that require licensure, the agency may revoke all licenses and impose actions under s. 408.814 and a fine of $1,000 per day, unless otherwise specified by authorizing statutes, against each licensee until such time as the appropriate license is obtained for the unlicensed operation.

(6) In addition to granting injunctive relief pursuant to subsection (2), if the agency determines that a person or entity is operating or maintaining a provider without obtaining a license and determines that a condition exists that poses a threat to the health, safety, or welfare of a client of the provider, the person or entity is subject to the same actions and fines imposed against a licensee as specified in this part, authorizing statutes, and agency rules.

(7) Any person aware of the operation of an unlicensed provider must report that provider to the agency.

408.813 Administrative fines.--As a penalty for any violation of this part, authorizing statutes, or applicable rules, the agency may impose an administrative fine. Unless the amount or aggregate limitation of the fine is prescribed by

authorizing statutes or applicable rules, the agency may establish criteria by rule for the amount or aggregate limitation of administrative fines applicable to this part, authorizing statutes, and applicable rules. Each day of violation constitutes a separate violation and is subject to a separate fine. For fines imposed by final order of the agency and not subject to further appeal, the violator shall pay the fine plus interest at the rate specified in s. 55.03 for each day beyond the date set by the agency for payment of the fine.

408.814 Moratorium; emergency suspension.--

(1) The agency may impose an immediate moratorium or emergency suspension as defined in s. 120.60 on any provider if the agency determines that any condition related to the provider or licensee presents a threat to the health, safety, or welfare of a client.

(2) A provider or licensee, the license of which is denied or revoked, may be subject to immediate imposition of a moratorium or emergency suspension to run concurrently with licensure denial, revocation, or injunction.

(3) A moratorium or emergency suspension remains in effect after a change of ownership, unless the agency has determined that the conditions that created the moratorium, emergency suspension, or denial of licensure have been corrected.

(4) When a moratorium or emergency suspension is placed on a provider or licensee, notice of the action shall be posted and visible to the public at the location of the provider until the action is lifted.

408.815 License or application denial; revocation.--

(1) In addition to the grounds provided in authorizing

statutes, grounds that may be used by the agency for denying and revoking a license or change of ownership application include any of the following actions by a controlling interest:

(a) False representation of a material fact in the license application or omission of any material fact from the application.

(b) An intentional or negligent act materially affecting the health or safety of a client of the provider.

(c) A violation of this part, authorizing statutes, or applicable rules.

(d) A demonstrated pattern of deficient performance.

(e) The applicant, licensee, or controlling interest has been or is currently excluded, suspended, or terminated from participation in the state Medicaid program, the Medicaid program of any other state, or the Medicare program.

(2) If a licensee lawfully continues to operate while a denial or revocation is pending in litigation, the licensee must continue to meet all other requirements of this part, authorizing statutes, and applicable rules and must file subsequent renewal applications for licensure and pay all licensure fees. The provisions of ss. 120.60(1) and 408.806(3)(c) shall not apply to renewal applications filed during the time period in which the litigation of the denial or revocation is pending until that litigation is final.

(3) An action under s. 408.814 or denial of the license of the transferor may be grounds for denial of a change of ownership application of the transferee.

408.816 Injunctions.--

(1) In addition to the other powers provided by this part,

authorizing statutes, and applicable rules, the agency may institute injunction proceedings in a court of competent jurisdiction to:

(a) Restrain or prevent the establishment or operation of a provider that does not have a license or is in violation of any provision of this part, authorizing statutes, or applicable rules. The agency may also institute injunction proceedings in a court of competent jurisdiction when a violation of this part, authorizing statutes, or applicable rules constitutes an emergency affecting the immediate health and safety of a client.

(b) Enforce the provisions of this part, authorizing statutes, or any minimum standard, rule, or order issued or entered into pursuant thereto when the attempt by the agency to correct a violation through administrative sanctions has failed or when the violation materially affects the health, safety, or welfare of clients or involves any operation of an unlicensed provider.

(c) Terminate the operation of a provider when a violation of any provision of this part, authorizing statutes, or any standard or rule adopted pursuant thereto exists that materially affects the health, safety, or welfare of a client.

Such injunctive relief may be temporary or permanent.

(2) If action is necessary to protect clients of providers from immediate, life-threatening situations, the court may allow a temporary injunction without bond upon proper proofs being made. If it appears by competent evidence or a sworn, substantiated affidavit that a temporary injunction should be issued, the court, pending the determination on final hearing,

shall enjoin the operation of the provider.

408.817 Administrative proceedings.--Administrative proceedings challenging agency licensure enforcement action shall be reviewed on the basis of the facts and conditions that resulted in the agency action.

408.818 Health Care Trust Fund.--Unless otherwise prescribed by authorizing statutes, all fees and fines collected under this part, authorizing statutes, and applicable rules shall be deposited into the Health Care Trust Fund, created in s. 408.16, and used to pay the costs of the agency in administering the provider program paying the fees or fines.

408.819 Rules.--The agency is authorized to adopt rules as necessary to administer this part. Any licensed provider that is in operation at the time of adoption of any applicable rule under this part or authorizing statutes shall be given a reasonable time under the particular circumstances, not to exceed 6 months after the date of such adoption, within which to comply with such rule, unless otherwise specified by rule.

408.820 Exemptions.--Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

(1) Laboratories authorized to perform testing under the Drug-Free Workplace Act, as provided under ss. 112.0455 and 440.102, are exempt from s. 408.810(5)-(10).

(2) Birth centers, as provided under chapter 383, are exempt from s. 408.810(7)-(10).

(3) Abortion clinics, as provided under chapter 390, are exempt from s. 408.810(7)-(10).

(4) Crisis stabilization units, as provided under parts I

and IV of chapter 394, are exempt from s. 408.810(8)-(10).

(5) Short-term residential treatment facilities, as provided under parts I and IV of chapter 394, are exempt from s. 408.810(8)-(10).

(6) Residential treatment facilities, as provided under part IV of chapter 394, are exempt from s. 408.810(8)-(10).

(7) Residential treatment centers for children and adolescents, as provided under part IV of chapter 394, are exempt from s. 408.810(8)-(10).

(8) Hospitals, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(9).

(9) Ambulatory surgical centers, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(10).

(10) Mobile surgical facilities, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(10).

(11) Private review agents, as provided under part I of chapter 395, are exempt from ss. 408.806(7), 408.810, and 408.811.

(12) Health care risk managers, as provided under part I of chapter 395, are exempt from ss. 408.806(7), 408.810, and 408.811.

(13) Nursing homes, as provided under part II of chapter 400, are exempt from s. 408.810(7).

(14) Assisted living facilities, as provided under part III of chapter 400, are exempt from s. 408.810(10).

(15) Home health agencies, as provided under part IV of chapter 400, are exempt from s. 408.810(10).

(16) Nurse registries, as provided under part IV of chapter 400, are exempt from s. 408.810(6) and (10).

(17) Companion services or homemaker services providers, as provided under part IV of chapter 400, are exempt from s. 408.810(6)-(10).

(18) Adult day care centers, as provided under part V of chapter 400, are exempt from s. 408.810(10).

(19) Adult family-care homes, as provided under part VII of chapter 400, are exempt from s. 408.810(7)-(10).

(20) Homes for special services, as provided under part VIII of chapter 400, are exempt from s. 408.810(7)-(10).

(21) Transitional living facilities, as provided under part VIII of chapter 400, are exempt from s. 408.810(7)-(10).

(22) Prescribed pediatric extended care centers, as provided under part IX of chapter 400, are exempt from s. 408.810(10).

(23) Home medical equipment providers, as provided under part X of chapter 400, are exempt from s. 408.810(10).

(24) Intermediate care facilities for persons with developmental disabilities, as provided under part XI of chapter 400, are exempt from s. 408.810(7).

(25) Health care services pools, as provided under part XII of chapter 400, are exempt from s. 408.810(6)-(10).

(26) Health care clinics, as provided under part XIII of chapter 400, are exempt from ss. 408.809 and 408.810(1), (6), (7), and (10).

(27) Clinical laboratories, as provided under part I of chapter 483, are exempt from s. 408.810(5)-(10).

(28) Multiphasic health testing centers, as provided under part II of chapter 483, are exempt from s. 408.810(5)-(10).

(29) Organ and tissue procurement agencies, as provided

under chapter 765, are exempt from s. 408.810(5)-(10).

Section 6. Paragraph (b) of subsection (1) of section 400.801, Florida Statutes, is amended to read:

400.801 Homes for special services.--

(1) As used in this section, the term:

(b) "Home for special services" means a site licensed by the agency prior to January 1, 2006, where specialized health care services are provided, including personal and custodial care, but not continuous nursing services.

Section 7. Subsections (1) and (3) of section 408.831, Florida Statutes, are amended to read:

408.831 Denial, suspension, or revocation of a license, registration, certificate, or application.--

(1) In addition to any other remedies provided by law, the agency may deny each application or suspend or revoke each license, registration, or certificate of entities regulated or licensed by it:

(a) If the applicant, licensee, or a licensee subject to this part which shares a common controlling interest with the applicant ~~registrant, or certificateholder, or, in the case of a corporation, partnership, or other business entity, if any officer, director, agent, or managing employee of that business entity or any affiliated person, partner, or shareholder having an ownership interest equal to 5 percent or greater in that business entity,~~ has failed to pay all outstanding fines, liens, or overpayments assessed by final order of the agency or final order of the Centers for Medicare and Medicaid Services, not subject to further appeal, unless a repayment plan is approved by the agency; or

(b) For failure to comply with any repayment plan.

(3) This section provides standards of enforcement applicable to all entities licensed or regulated by the Agency for Health Care Administration. This section controls over any conflicting provisions of chapters 39, ~~381,~~ 383, 390, 391, ~~393,~~ 394, 395, 400, 408, 468, 483, and 765 ~~641~~ or rules adopted pursuant to those chapters.

Section 8. In case of conflict between the provisions of part II of chapter 408, Florida Statutes, and the authorizing statutes governing the licensure of health care providers by the Agency for Health Care Administration found in s. 112.0455 and chapters 383, 390, 394, 395, 400, 440, 483, and 765, Florida Statutes, the provisions of part II of chapter 408, Florida Statutes, shall prevail.

Section 9. All provisions that apply to the entities specified in s. 408.802, Florida Statutes, as created by this act, in effect on October 1, 2006, that provide for annual licensure fees are hereby adjusted to provide for biennial licensure fees with a corresponding doubling of the amount.

Section 10. The Legislature recognizes that there is a need to conform the Florida Statutes to the policy decisions reflected in this act and that there may be a need to resolve apparent conflicts between any changes or additions to the authorizing statutes, as defined in s. 408.803, Florida Statutes, or any other legislation that has been or may be enacted during 2006 and this chapter 408, Florida Statutes, as amended by this act. Therefore, in the interim between this act becoming a law and the 2007 Regular Session of the Legislature or an earlier special session addressing this issue, the Division of Statutory Revision

shall provide the relevant substantive committees of the Senate and the House of Representatives with assistance, upon request, to enable such committees to prepare draft legislation to conform the Florida Statutes and any legislation enacted during 2006 to the provisions of this act.

Section 11. For the purpose of staggering license expiration dates, the Agency for Health Care Administration may issue a license for less than a 2-year period to those providers making the transition from annual to biennial licensure as authorized in this act. The agency shall charge a prorated licensure fee for this shortened period. This authority shall expire September 30, 2008.

Section 12. This act shall take effect October 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCR 06-04 Electronic Prescribing
SPONSOR(S): Health Care Regulation Committee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Health Care Regulation Committee		Bell AJB	Mitchell
1)			
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

With rapid change in new information technologies the development of electronic prescribing practices is integral to the achievement of state and national goals for electronic medical records. Current regulations regarding written prescriptions are problematic for prescriptions electronically generated.

The Proposed Committee Bill (PCB) on Electronic Prescribing allows for the development and regulation of electronic prescribing practices and provides protections for consumers. It creates one new provision in state statute and amends four others.

The bill defines "records custodians" and provides that all those with access to medical or prescription records abide by confidentiality and disclosure requirements. The bill establishes information that must be contained in electronic prescriptions. The bill regulates the use of electronic prescribing software and forbids that such software interfere with prescribing decisions at the point of care, or direct practitioners toward choosing particular pharmacies. Finally, the bill provides mechanisms to ensure that patients receive brand name drugs, when such drugs are medically necessary, and not substitutes, when prescribed electronically.

According to the Department of Health, there is no fiscal impact to implement the provisions in this bill.

The effective date of the bill is upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill removes regulatory barriers to streamline the process of prescribing prescription drugs electronically.

Safeguard Individual Liberty – The bill protects the rights of consumers and their health care providers to determine appropriate pharmaceuticals and purchase from pharmacies of their choice; and to guarantee the confidentiality of medical records and prescriptions.

B. EFFECT OF PROPOSED CHANGES:

PRESENT SITUATION

Florida law permits electronic prescriptions under chapter 456, F.S., and authorizes the regulation of the practice of pharmacy by the Florida Board of Pharmacy. Section 465.003(14), F.S., further defines "prescription" to be any order for drugs or medicinal supplies written or transmitted by any means of communication by a licensed practitioner and intended to be dispensed by a pharmacist. Prescriptions may be transmitted from practitioners to pharmacies orally or through writing; and pharmacies may transfer prescriptions by any means, including electronic, under specified conditions.

Medical Records

Currently only certain health care practitioners and their employers (if agreed by contract) are considered records owners and subject to limitations on the handling of patient medical records under s. 456.072, F.S. Other individuals who later come into possession of patient medical records are not subject to these limitations.

Legible Prescribing Law

The Legible Prescribing Law, codified in s. 456.42, F.S, requires that all written prescription drugs must:

- Be legibly printed or typed;
- Contain the name of the prescribing practitioner;
- Contain the name and strength of the drug, the quantity of the drug in both textual and numerical formats;
- Contain directions for use;
- Be dated and signed with the month written in textual letters; and
- Be signed by the prescribing practitioner on the day when issued.

In order to fill a written prescription, Florida law requires that the prescription be signed by the prescribing practitioner. This poses a problem for electronically generated prescriptions.

Generic Substitution

Currently, under s. 456.025, F.S., a pharmacist may substitute a generic drug for a brand name drug when any written prescription does not include the words, "MEDICALLY NECESSARY" written by the prescribing practitioner. It is technically difficult for the prescribing practitioner to write on electronically generated prescriptions.

Electronic prescribing is integral to the achievement of state and national goals for integrated electronic medical records. The bill creates one and amends four provisions in state statute for the development of electronic prescribing practices, the regulation of electronic prescribing software, and the protection of patient rights.

EFFECTS OF THE BILL

Definition of Records Custodian

The bill amends s. 456.057, F.S., to define "records custodian" and to require records custodians and records owners to maintain records and documents as provided under the confidentiality and disclosure requirements of this section. The bill provides that all those with access to medical or prescription records abide by confidentiality and disclosure requirements. According to the Department of Health (DOH), this helps address confidentiality concerns when patient medical records are abandoned by the practitioner. This provision is subject to enforcement by the Office of Attorney General through injunctive relief and fines of up to $5,000 per violation.

Requirements for Electronic Prescriptions

The bill amends s. 456.42, F.S., to provide requirements for prescriptions that are electronically generated and transmitted. The bill requires that the electronic prescription contain the name of the prescribing practitioner, name and strength of the drug prescribed, quantity of the drug prescribed in numerical format (in contrast to handwritten prescriptions that require both textual and numerical format), directions for use of the drug, date, and signature by practitioner only on the day issued. The signature may be in an electronic format as defined by s. 668.003(4).

Consumer Choice of Pharmacy

The bill creates s. 456.43, F.S., to regulate electronic prescribing software for the protection of consumers and patient's rights. As electronic prescribing becomes more prevalent it is necessary to protect consumer choice when choosing a pharmacy.This section provides restrictions and establishes that electronic prescribing software:

- Shall not interfere with patient's freedom to choose a pharmacy;
- Shall not attempt to influence, through economic incentives or otherwise, the prescribing decision of a physician at the "point of care"—the time that the practitioner or agent is in the act of prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.
- Shall be permitted to show information regarding a payor's formulary as long as nothing is designed to preclude or make more difficult the act of the patient or physician selecting any particular pharmacy or pharmaceutical.

Protections against Generic Substitution of Brand Name Drugs

The bill amends s. 456.025, F.S., to provide mechanisms to ensure that patients receive brand name drugs and not generic substitutes, when brand name drugs are medically necessary. The bill ensures that a pharmacist may fill electronically generated prescriptions with the brand name drug if the prescription reflects that it is medically necessary without requiring the prescribing practitioner to write the words, "MEDICALLY NECESSARY."

The effective date of the bill is July 1, 2006.

BACKGROUND

Electronic prescribing (e-prescribing) utilizes computers and automated data systems rather than handwritten communications to generate prescriptions, and is the future standard practice in prescription writing. Although e-prescribing rates today vary between 5 percent and 18 percent for

physicians, usage is increasing[1] due to initiatives at the national and state levels, and because of independent efforts by health care providers and pharmacists. In June 2005, President Bush called for most Americans to have electronic health records[2] within ten years. The Florida Health Information Network was developed by the Agency for Health Care Administration (AHCA) to facilitate the development of a statewide privacy-protected health information infrastructure network as recommended by the Governor's Health Information Infrastructure Advisory Board. The program has received funding from the Florida Legislature to support personnel and grant programs aimed at developing regional health information exchanges and to encourage the use of electronic health records.[3] Electronic prescribing is an integral component in the fulfillment of these national and state goals.

Concerns with patient safety, the efficiency of care, and integrated medical records are the key objectives driving efforts for electronic prescribing. More than 4 billion prescriptions are written each year[4] and therefore even small improvements in the prescribing process will translate into significant healthcare cost and safety benefits. Studies suggest that the national savings from universal adoption of electronic prescribing systems could be as high as $27 billion, due to a combination of injury prevention, better utilization of drugs[5], and efficiency both at the point of care and subsequent to treatment.

Security Measures Used by Electronic Prescribing Networks

Currently, there are a number of methods through which electronic networks secure confidentiality and data integrity. These features include credentialing, where prescribers and pharmacies are enrolled in a network through access authorization; user ID and password for authentication and access to electronic prescribing software; the use of network-assigned electronic signatures; and the transmission of prescription messages through a private leased line or through the Internet using a virtual private network connection or protocol.[6]

Benefits of Electronic Prescribing

Reduction of potential errors of handwriting and transcription

The prescribing process is error-prone. Adverse drug events (ADE) are the 4th leading cause of death[7] and cost as much as $136 billion a year[8]. Among ADE's, 7,000 deaths a year are attributed to prescription error[9]. Causes of errors include illegible handwriting, wrong dosage, and the overlooking of dangerous drug-drug or drug-allergy interactions. Medication errors further account for 1 out of 131 ambulatory care deaths.[10] As a solution for a portion of these errors, computer-assisted prescriptions have been shown to cut errors by 70% over handwritten prescriptions.[11] In addition to improving the readability of scripts and the accuracy of transcription from the prescription to the pharmacy, a reduction in errors accomplished by electronic prescribing is due to information made available to doctors about the correct dosage, use instructions, and other aspects of the prescription. At the point of care, electronic prescribing systems can provide an overall medication management process by

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[1] Ferris, Nancy. 11/2/05. "CMS finalizes e-prescribing rules." *Government Health.* www.govhealthit.com/article91285-11-02-05-Web.
[2] According to the Florida Senate Interim Project 2006-135, "An electronic health record is a digital collection of information from a patient's medical history that may include diagnoses, prescribed medications, vital signs, immunizations, and personal characteristics."
[3] Agency for Health Care Administration press release, January 6, 2006; http://www.fdhc.state.fl.us/dhit/press_release.shtml.
[4] AllScripts analysis of e-prescribing at http://www.allscripts.com/sInsClnclnfo.aspx
[5] Agency for Healthcare Research and Quality. MEPS Highlights #11: Distribution of health care expenses, 1999.
[6] National Committee on Vital and Health Statistics. http://www.cdc.gov/nchs/data/ncvhs/nchvs50th.pdf
[7] Committee on Quality of Health Care in America: Institute of Medicine. "To err is human: building a safer health system." Washington, D.C.: National Academy Press, 2000.
[8] Lazarou, J., Pomeranz, B., Corey, PN. "Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA*. 1998; 279:1200-1205.
[9] Johnson, JA., Bootman, JL. "Drug-related morbidity and mortality: a cost-of-illness model." *Arch Intern Med.* 1995; 155:1949-1956.
[10] "Electronic Prescribing: Toward Maximum Value and Rapid Adoption." A report of the *Electronic Prescribing Initiative.* Washington, D.C., April 14, 2004.
[11] "HHS Accelerates Use of E-Prescribing and Electronic Health Records." *Press Release from the US Department of Health and Human Services.* 11/5/2005. http://biz.yahoo.com/prnews/051005/dcw035.html?.v=29&printer=1.

performing checks against the patient's current medications, duplicate therapies, medical history, diagnoses, body weight, age, and more. The system then alerts the physician if problems are found.

Integration of prescription information into the electronic medical record

Electronic prescribing can further contribute to the integration of the prescription into a patient's consolidated medical record. Access to information about a patient's formulary can guide physicians to consider formulary-based drug coverage, including on-formulary alternatives and co-pay information. By checking with healthcare formularies at point-of-care, generic substitutions and generic first-line therapy choices are encouraged, thus reducing patient costs.

Efficiency

Electronic prescribing increases efficiency for physicians, patients, and pharmacists. At the point-of-care, electronic prescribing saves time for the physician's staff. For many practitioners, it is quicker to e-prescribe than to have a nurse spend time calling in a refill for the drug.[12] Physicians can expect fewer callbacks from pharmacies to clarify prescription details and refill renewal authorizations that are completed in a fraction of the time, so that more time can be dedicated to patient care and other activities.[13] A 2003 survey of Boston area physicians found that 88 percent of those surveyed reported that they and their staff spend almost one-third of their time responding to phone calls from pharmacies regarding prescriptions, and that these call-backs interrupt office flow and reduce productivity related to chart-pulls, re-filing charts, faxing prescriptions, and so on.[14] For patients, electronic prescribing means eliminated or significantly reduced waiting times at pharmacies.[15] Benefits in efficiency for pharmacists are also significant. Because all necessary prescription information is transmitted and received, more time can be spent with customers. Electronic prescribing improves record keeping, reduces phone calls and faxes, and more readily alerts pharmacists to possible drug contraindications within a patient's file. Approximately 900 million prescription-related calls are made annually, for refills, questions and clarifications; and electronic prescribing reduces the expense of this for all parties.[16]

Protecting Against Abuses of Electronic Prescribing

Although electronic prescribing does have the demonstrated potential to save lives, time, and money, unsecured systems could lead to forgery, fraud, unfair trade practices, or the loss of patient confidentiality. In developing electronic programs it is critical that precautions be taken to expand consumer protection. Among these measures, the patient's right to choose medications and pharmacies should be protected; and therefore, software used in electronic prescribing should be prevented from directing the practitioner toward specific medications or pharmacies through pop-up ads or marketing of any other kind. Patient confidentiality must also be protected; and therefore, electronic data services ("records custodians") should be bound by the same specified requirements for confidentiality and disclosure as pharmacies and physicians already are. It is also important that electronic prescriptions include the same level of information as paper prescriptions; detailing patient and physician names, drug name and strength, quantity and directions for use of the drug, date, electronic signature, and an option to prevent automatic substitution of brand name drugs with generic drugs in cases where the brand name drug is medically necessary for the patient.

Expansion of Electronic Prescribing in Medicare and Florida Medicaid

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, electronic-prescribing is optional for physicians and pharmacies. However, starting on January 1, 2006, drugs

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[12] Baldwin, Gary. 10/17/2005. "E-prescribing eliminates wait." *Health Leaders.* http://www..healthleaders.com/news/print.php?contentid=73529.

[13] Institute of Medicine, Center for Information Technology Leadership, in Walgreens presentation on e-prescribing.

[14] "Boston Area Physicians Embrace E-Prescribing Technology as a Tool To Improve Healthcare". Medco Health Solutions, Inc. – News and Pressroom article on 2/7/2003. http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=MHS&script=410&layout=-6&item_id=442064

[15] Baldwin, Gary. 10/17/2005. "E-prescribing eliminates wait." *Health Leaders.* http://www..healthleaders.com/news/print.php?contentid=73529.

[16] Healthcare Information and Management Systems Society at http://www.himss.org/ASP/topics_eprescribing.asp.

covered under Medicare Part D are required to support electronic prescribing.[17] The Act has also called for the creation of a grant program that supports the implementation and adoption of electronic prescribing technology beginning in 2007.

The Florida Medicaid program has used an electronic prescribing system since the summer of 2002. Three thousand of the state's highest prescribing (by volume) physicians were given interactive handheld computers that load information on drugs, formularies, and the previous 100 days of prescription history. This represents physicians writing 80 percent of all Medicaid prescriptions in FL, which involves approximately 25 million transactions per year.[18] Florida Medicaid program staff estimate that about $2 million is saved each month by the use of the electronic prescribing system, and that the program has demonstrated the potential for electronic prescribing to save lives as well.[19]

C. SECTION DIRECTORY:

Section 1. – Amends s. 456.057, F.S., to provide definitions for "records custodian" and to require records custodians and records owners to maintain records and documents as provided under the confidentiality and disclosure requirements of the section.

Section 2. – Amends s. 456.42, F.S., to provide requirements for prescriptions that are electronically generated and transmitted.

Section 3. – Creates s. 456.43, F.S., to regulate electronic prescribing software for the protection of consumers and patient's rights.

Section 4. – Amends s. 456.025, F.S., to prevent the substitution of generic drugs when brand name drugs are medically necessary, when a prescription is electronically transmitted and generated.

Section 5. – Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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[17] For complete standards see "Government announces ePRESCRIPTION standards for drug plans" by Caroline Broder, Healthcare IT News. 11/2/2005. www.healthcareitnews.com/NewsArticleView.aspz?ContentID=3940.
[18] Roop, Liz. 2005. "State by state programs" eMPOWEPrescription. www.gsm.com, or 813-258-4747.
[19] The Florida Senate Interim Project Report 2006-135.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rulemaking authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to medical records; amending s. 456.057, F.S.; providing definitions; requiring a health care practitioner's employer who is a records owner and a records custodian to comply with specified requirements for confidentiality and disclosure; amending s. 456.42, F.S.; providing requirements for prescriptions of medicinal drugs by health care practitioners that are electronically generated and transmitted; creating s. 456.43, F.S.; regulating electronic prescribing for medicinal drugs; providing restrictions for electronic prescribing software; providing definitions; authorizing electronic prescribing software to show information regarding a payor's formulary under certain circumstances; amending s. 465.025, F.S.; specifying requirements for a prescriber to prevent generic substitution for brand name drugs when a prescription is electronically transmitted and generated; amending s. 381.028, F.S.; correcting a cross-reference; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Present subsections (3) through (19) of section 456.057, Florida Statutes, are renumbered as subsections (5) through (21), respectively, and new subsections (3) and (4) are added to that section to read:

456.057 .Ownership and control of patient records; report or copies of records to be furnished.--

(3) As used in this section, the term "records custodian"

means any person or entity that:

(a) Maintains documents that are authorized in subsection (2); or

(b) Obtains medical records from a records owner.

(4) Any health care practitioner's employer who is a records owner and any records custodian shall maintain records or documents as provided under the confidentiality and disclosure requirements of this section.

Section 2. Section 456.42, Florida Statutes, is amended to read:

456.42 Written prescriptions for medicinal drugs.--A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in both textual and numerical formats, and the directions for use of the drug; must be dated with the month written out in textual letters; and must be signed by the prescribing practitioner on the day when issued. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined by s. 668.003(4).

Section 3. Section 456.43, Florida Statutes, is created to

read:

456.43 Electronic prescribing for medicinal drugs.--

(1) Electronic prescribing shall not interfere with a patient's freedom to choose a pharmacy.

(2) Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a physician at the point of care. Such means shall not be triggered or in specific response to the input, selection, or act of a physician or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.

(a) The term "prescribing decision" means a physician's decision to prescribe a certain pharmaceutical or direct a patient to a certain pharmacy.

(b) The term "point of care" means the time that a physician or his or her agent is in the act of prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.

(3) Electronic prescribing software may show information regarding a payor's formulary as long as nothing is designed to preclude or make more difficult the act of a physician or patient selecting any particular pharmacy or pharmaceutical.

Section 4. Subsection (2) of section 465.025, Florida Statutes, is amended to read:

465.025 Substitution of drugs.--

(2) A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser,

substitute a less expensive, generically equivalent drug product that is:

(a) Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and

(b) Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed,

unless the prescriber writes the words "MEDICALLY NECESSARY," in her or his own handwriting, on the face of a written prescription; ~~or~~ unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

Section 5. Paragraph (c) of subsection (7) of section 381.028, Florida Statutes, is amended to read:

381.028 Adverse medical incidents.--

(7) PRODUCTION OF RECORDS.--

(c)1. Fees charged by a health care facility for copies of records requested by a patient under s. 25, Art. X of the State Constitution may not exceed the reasonable and actual cost of complying with the request, including a reasonable charge for the

staff time necessary to search for records and prevent the disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means as required by the Health Insurance Portability and Accountability Act of 1996 or its implementing regulations. The health care facility may require payment, in full or in part, before acting on the records request.

2. Fees charged by a health care provider for copies of records requested by a patient under s. 25, Art. X of the State Constitution may not exceed the amount established under s. 456.057(18) ~~(16)~~, which may include a reasonable charge for the staff time necessary to prevent the disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means as required by the Health Insurance Portability and Accountability Act of 1996 or its implementing regulations. The health care provider may require payment, in full or in part, before acting on the records request.

Section 6. This act shall take effect July 1, 2006.